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No. 2024-1285

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors,

On Appeal from the United States International Trade Commission
in Investigation No. 337-TA-1276

NON-CONFIDENTIAL JOINT APPENDIX

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CERTIFICATE OF SERVICE

CONFIDENTIAL MATERIAL OMITTED

The material omitted from Appx9; Appx36; Appx41-44; Appx46-48; Appx108; Appx119; Appx121-122; Appx150-151; Appx153-154; Appx156-158; Appx187-190; Appx192-194; Appx196; Appx198; Appx218; Appx220-222; Appx265-276; Appx373; Appx13067-13069; Appx21846; Appx22790; Appx22954; Appx22956-22958; Appx22985; Appx22990; Appx23139; Appx23166; Appx23171-23174; Appx23238; Appx23249; Appx23251-23252; Appx23280-23281; Appx23283-23284; Appx23286-23288; Appx23317-23320; Appx23322-Appx23323; Appx23326; Appx23328; Appx23348; Appx23350-23352; Appx23395-23406; Appx23656; Appx23658; Appx23681-23682; 23688; Appx23791; Appx24147-24148; Appx40795-40798; Appx40996-40999; Appx41019-41026; Appx41029-41030; Appx41058-41062; Appx41077-41080; Appx41094-41097; Appx41108-41110; Appx51900-51924; Appx52602-52606; Appx52609; Appx52642-52645; Appx52791-52795; Appx52822-52824; Appx52911-52912; Appx52939-52941; Appx52980-52982; Appx53016-53019; Appx60425-60431; Appx60432-60434; Appx70322-70355; Appx70774; Appx70781-70783; and Appx70841-70876 contains Apple's confidential competitively sensitive product information subject to the Administrative Protective Order; the material omitted from Appx4579 and Appx53459-53461 contains competitively sensitive information regarding confidential agreements; the material omitted from Appx23439; Appx23441-23446; Appx23448; Appx23450-23453; Appx23455-23458; Appx23462; Appx23617; Appx23621; Appx23659-23665; Appx25251; Appx40483; Appx40582-40584; Appx40600-40601; Appx40605; Appx40652-40655; Appx40658-40662; Appx53491; Appx53492; Appx53497; Appx53499; Appx53503; Appx53506; Appx65064-65075; Appx65075; Appx65104-65105; Appx65315; Appx65321-65232; and Appx71223-71244 contains Masimo's confidential competitively sensitive financial information subject to the Administrative Protective Order; the material omitted from Appx311-316; Appx23667-23674; Appx40579-40581; Appx40585-40599; Appx40602-40604; Appx40610-40614; and Appx40631-40633 contains Masimo's confidential competitively sensitive financial and manufacturing information subject to the Administrative Protective Order; the material omitted from Appx473-474; Appx62; and Appx23176-23178 contains Masimo's confidential competitively sensitive manufacturing information subject to the Administrative Protective Order; the material omitted from Appx13047; Appx14129-14140; Appx205-206; Appx211; Appx21848; Appx22282-22286; Appx23197; Appx23204; Appx23335-23336; Appx23341; Appx23408-23416; Appx23434-23436; Appx23454; Appx23642; Appx23644-23645; Appx23647-23649; Appx23685-23687; Appx23693-23697; Appx23704; Appx25253-25260; Appx278-286; Appx2809-

2852; Appx2923-2937; Appx304-306; Appx309; Appx3708; Appx3710-3711; Appx3718; Appx3722; Appx3725; Appx3727; Appx3732; Appx3733; Appx3735; Appx40229-40232; Appx40346-40371; Appx40407-40422; Appx40431-40434; Appx40438-40442; Appx40486-40494; Appx40495-40506; Appx40512-40521; Appx40525-40528; Appx40547-40555; Appx40560-40574; Appx40803-40822; Appx41217-41221; Appx41350-41356; Appx53070-53095; Appx53107-53151; Appx53222-53234; Appx53236-53252; Appx53256-53361; Appx53362-53365; Appx53813-53838; Appx53927-53941; Appx54064-54226; Appx54227-54266; Appx55229-55354; Appx55359-55376; Appx55386-55399; Appx57317-57324; Appx57394--57409; Appx57410-57412; Appx57615-57618; Appx60136-60153; Appx60184-60212; Appx65014-65019; Appx65022-65025; Appx65028-65037; Appx65040-65074; Appx65207; Appx65224; Appx65267-65268; Appx67; Appx6701-6703; Appx6705; Appx6732-6736; Appx6852-6854; Appx6937-6950; Appx70475; Appx70484-70491; Appx70504-70513; Appx70518-70559; Appx70610-70613; Appx70615-70617; Appx70619-70628; Appx70833-70835; Appx70948-70950; Appx70955-70956; and Appx74 contains Masimo's confidential competitively sensitive product information subject to the Administrative Protective Order; the material omitted from Appx23707-23709; Appx318; Appx320-328; Appx40634; and Appx70592-70594 contains Masimo's confidential competitively sensitive product and financial information subject to the Administrative Protective Order; the material omitted from Appx176; Appx179; Appx22788-22789; and Appx22791 contains Masimo's confidential information detailing non-public patent prosecution subject to the Administrative Protective Order; the material omitted from Appx404-405; Appx457; Appx460-461; Appx464; Appx24103-24104; Appx25387; and Appx25389 contains Apple's confidential competitively sensitive financial and sales information subject to the Administrative Protective Order; the material omitted from Appx52602-52608 contains confidential competitively sensitive product of a third party.

PTO/AIA/14 (11-15)
CX1623

Approved for use through 04/30/2017. OMB 0651-0032

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	MASCER.002C2
		Application Number	
Title of Invention	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS		

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MASCER.002C2

PATENT

**MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE
MEASUREMENT OF BLOOD CONSTITUENTS**

RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application No. 12/829,352 filed July 1, 2010, which is a continuation of U.S. Patent Application No. 12/534,827 filed August 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/534,827 is also a continuation of U.S. Patent Application No. 12/497,528 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. U.S. Patent Application No. 12/534,827 is also a continuation of U.S. Patent Application No. 12/497,523 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008.

[0002] This application is related to the following U.S. Patent Applications:

<u>App. No.</u>	<u>Filing Date</u>	<u>Title</u>	<u>Attorney Docket</u>
12/497,528	7/2/09	<i>Noise Shielding for Noninvasive Device Contoured Protrusion for Improving</i>	MASCER.006A
12/497,523	7/2/09	<i>Spectroscopic Measurement of Blood Constituents</i>	MASCER.007A
12/497,506	7/2/09	<i>Heat Sink for Noninvasive Medical Sensor</i>	MASCER.011A
12/534,812	8/3/09	<i>Multi-Stream Sensor Front Ends for Non- Invasive Measurement of Blood Constituents</i>	MASCER.003A
12/534,823	8/3/09	<i>Multi-Stream Sensor for Non-Invasive Measurement of Blood Constituents</i>	MASCER.004A
12/534,825	8/3/09	<i>Multi-Stream Emitter for Non-Invasive Measurement of Blood Constituents</i>	CERCA.005A

[0003] The foregoing applications are hereby incorporated by reference in their entirety.

BACKGROUND

[0004] The standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter. Devices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood. After attenuation by tissue and fluids of the measurement site, a photodetection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light. A signal processing device(s) process the detector(s) signal(s) and outputs a measurement indicative of a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, other physiological parameters, or other data or combinations of data useful in determining a state or trend of wellness of a patient.

[0005] In noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.

SUMMARY

[0006] This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

[0007] In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the noninvasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the non-invasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

[0008] In an embodiment, a noninvasive device is capable of producing a signal responsive to light attenuated by tissue at a measurement site. The device may comprise an optical source and a plurality of photodetectors. The optical source is configured to emit optical radiation at least at wavelengths between about 1600 nm and about 1700 nm. The photodetectors are configured to detect the optical radiation from said optical source after attenuation by the tissue of the measurement site and each output a respective signal stream responsive to the detected optical radiation.

[0009] In an embodiment, a noninvasive, physiological sensor is capable of outputting a signal responsive to a blood analyte present in a monitored patient. The sensor may comprise a sensor housing, an optical source, and photodetectors. The optical source is positioned by the housing with respect to a tissue site of a patient when said housing is applied to the patient. The photodetectors are

positioned by the housing with respect to said tissue site when the housing is applied to the patient with a variation in path length among at least some of the photodetectors from the optical source. The photodetectors are configured to detect a sequence of optical radiation from the optical source after attenuation by tissue of the tissue site. The photodetectors may be each configured to output a respective signal stream responsive to the detected sequence of optical radiation. An output signal responsive to one or more of the signal streams is then usable to determine the blood analyte based at least in part on the variation in path length

[0010] In an embodiment, a method of measuring an analyte based on multiple streams of optical radiation measured from a measurement site is provided. A sequence of optical radiation pulses is emitted to the measurement site. At a first location, a first stream of optical radiation is detected from the measurement site. At least at one additional location different from the first location, an additional stream of optical radiation is detected from the measurement site. An output measurement value indicative of the analyte is then determined based on the detected streams of optical radiation.

[0011] In various embodiments, the present disclosure relates to an interface for a noninvasive sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. In an embodiment, the front-end is comprised of switched-capacitor circuits that are capable of handling multiple streams of signals from the optical detectors. In another embodiment, the front-end comprises transimpedance amplifiers that are capable of handling multiple streams of input signals. In addition, the transimpedance amplifiers may be configured based on the characteristics of the transimpedance amplifier itself, the characteristics of the photodiodes, and the number of photodiodes coupled to the transimpedance amplifier.

[0012] In disclosed embodiments, the front-ends are employed in noninvasive sensors to assist in measuring and detecting various analytes. The disclosed noninvasive sensor may also include, among other things, emitters and detectors positioned to produce multi-stream sensor information. An artisan will recognize that the noninvasive sensor may have different architectures and may

include or be coupled to other components, such as a display device, a network interface, and the like. An artisan will also recognize that the front-ends may be employed in any type of noninvasive sensor.

[0013] In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of transimpedance amplifiers configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

[0014] In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of switched capacitor circuits configured to convert the signals from the plurality of detectors into a digital output signal having a stream for each of the plurality of detectors; and an output configured to provide the digital output signal.

[0015] In an embodiment, a conversion processor for a physiological, noninvasive sensor comprises: a multi-stream input configured to receive signals from a plurality of detectors in the sensor, wherein the signals are responsive to optical radiation from a tissue site; a modulator that converts the multi-stream input into a digital bit-stream; and a signal processor that produces an output signal from the digital bit-stream.

[0016] In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of respective transimpedance amplifiers for each detector configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

[0017] In certain embodiments, a noninvasive sensor interfaces with tissue at a measurement site and deforms the tissue in a way that increases signal gain in certain desired wavelengths.

[0018] In some embodiments, a detector for the sensor may comprise a set of photodiodes that are arranged in a spatial configuration. This spatial configuration may allow, for example, signal analysis for measuring analytes like glucose. In various embodiments, the detectors can be arranged across multiple locations in a spatial configuration. The spatial configuration provides a geometry having a diversity of path lengths among the detectors. For example, the detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction.

[0019] In an embodiment, a physiological, noninvasive detector is configured to detect optical radiation from a tissue site. The detector comprises a set of photodetectors and a conversion processor. The set of photodetectors each provide a signal stream indicating optical radiation from the tissue site. The set of photodetectors are arranged in a spatial configuration that provides a variation in path lengths between at least some of the photodetectors. The conversion processor that provides information indicating an analyte in the tissue site based on ratios of pairs of the signal streams.

[0020] The present disclosure, according to various embodiments, relates to noninvasive methods, devices, and systems for measuring a blood analyte, such as glucose. In the present disclosure, blood analytes are measured noninvasively based on multi-stream infrared and near-infrared spectroscopy. In some embodiments, an emitter may include one or more sources that are configured as a point optical source. In addition, the emitter may be operated in a manner that allows for the measurement of an analyte like glucose. In embodiments, the emitter may comprise a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In addition, in order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. The emitter may also have its duty cycle modified to achieve a desired SNR.

[0021] In an embodiment, a multi-stream emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a set of optical sources arranged as a point optical source; and a driver

configured to drive the at least one light emitting diode and at least one optical source to transmit near-infrared optical radiation at sufficient power to measure an analyte in tissue that responds to near-infrared optical radiation.

[0022] In an embodiment, an emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a point optical source comprising an optical source configured to transmit infrared and near-infrared optical radiation to a tissue site; and a driver configured to drive the point optical source at a sufficient power and noise tolerance to effectively provide attenuated optical radiation from a tissue site that indicates an amount of glucose in the tissue site.

[0023] In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is transmitted at a power that is higher than the first power.

[0024] In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is then transmitted, at a second power that is higher than the first power.

[0025] For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the inventions have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] Throughout the drawings, reference numbers can be re-used to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the inventions described herein and not to limit the scope thereof.

[0027] FIGURE 1 illustrates a block diagram of an example data collection system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure;

[0028] FIGURES 2A – 2D illustrate an exemplary handheld monitor and an exemplary noninvasive optical sensor of the patient monitoring system of Figure 1, according to embodiments of the disclosure;

[0029] FIGURES 3A – 3C illustrate side and perspective views of an exemplary noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

[0030] FIGURE 3D illustrates a side view of another example noninvasive sensor housing including a heat sink, according to an embodiment of the disclosure;

[0031] FIGURE 3E illustrates a perspective view of an example noninvasive sensor detector shell including example detectors, according to an embodiment of the disclosure;

[0032] FIGURE 3F illustrates a side view of an example noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

[0033] FIGURES 4A through 4C illustrate top elevation, side and top perspective views of an example protrusion, according to an embodiment of the disclosure;

[0034] FIGURE 5 illustrates an example graph depicting possible effects of a protrusion on light transmittance, according to an embodiment of the disclosure;

[0035] FIGURES 6A through 6D illustrate perspective, front elevation, side and top views of another example protrusion, according to an embodiment of the disclosure;

[0036] FIGURE 6E illustrates an example sensor incorporating the protrusion of FIGURES 6A through 6D, according to an embodiment of the disclosure;

[0037] FIGURES 7A through 7B illustrate example arrangements of conductive glass that may be employed in the system of FIGURE 1, according to embodiments of the disclosure.

[0038] FIGURES 8A through 8D illustrate an example top elevation view, side views, and a bottom elevation view of the conductive glass that may be employed in the system of FIGURE 1, according to embodiments of the disclosure;

[0039] FIGURE 9 shows example comparative results obtained by an embodiment of a sensor;

[0040] FIGURES 10A and 10B illustrate comparative noise floors of various embodiments of the present disclosure;

[0041] FIGURE 11A illustrates an exemplary emitter that may be employed in the sensor, according to an embodiment of the disclosure;

[0042] FIGURE 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring blood constituents, according to an embodiment of the disclosure;

[0043] FIGURE 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

[0044] FIGURE 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure.

[0045] FIGURE 12A illustrates an example detector portion that may be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

[0046] FIGURES 12B through 12D illustrate exemplary arrangements of detectors that may be employed in an embodiment of the sensor, according to some embodiments of the disclosure;

[0047] FIGURES 12E through 12H illustrate exemplary structures of photodiodes that may be employed in embodiments of the detectors, according to some embodiments of the disclosure;

[0048] FIGURE 13 illustrates an example multi-stream operation of the system of FIGURE 1, according to an embodiment of the disclosure;

[0049] FIGURE 14A illustrates another example detector portion having a partially cylindrical protrusion that can be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

[0050] FIGURE 14B depicts a front elevation view of the partially cylindrical protrusion of FIGURE 14A;

[0051] FIGURES 14C through 14E illustrate embodiments of a detector submount;

[0052] FIGURES 14F through 14H illustrate embodiment of portions of a detector shell;

[0053] FIGURE 14I illustrates a cutaway view of an embodiment of a sensor;

[0054] FIGURES 15A through 15F illustrate embodiments of sensors that include heat sink features;

[0055] FIGURES 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described herein;

[0056] FIGURE 15I illustrates an exemplary architecture for a transimpedance-based front-end that may be employed in any of the sensors described herein;

[0057] FIGURE 15J illustrates an exemplary noise model for configuring the transimpedance-based front-ends shown in FIGURE 15I;

[0058] FIGURE 15K shows different architectures and layouts for various embodiments of a sensor and its detectors;

[0059] FIGURE 15L illustrates an exemplary architecture for a switched-capacitor-based front-end that may be employed in any of the sensors described herein;

[0060] FIGURES 16A and 16B illustrate embodiments of disposable optical sensors;

[0061] FIGURE 17 illustrates an exploded view of certain components of an example sensor; and

[0062] FIGURES 18 through 22 illustrate various results obtained by an exemplary sensor of the disclosure.

DETAILED DESCRIPTION

[0063] The present disclosure generally relates to non-invasive medical devices. In the present disclosure, a sensor can measure various blood constituents or analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes or percentages thereof (e.g., saturation) based on various combinations of features and components.

[0064] In various embodiments, the present disclosure relates to an interface for a noninvasive glucose sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. The front-end may comprise, among other things, switched capacitor circuits or transimpedance amplifiers. In an embodiment, the front-end may comprise switched capacitor circuits that are configured to convert the output of sensor's detectors into a digital signal. In another embodiment, the front-end may comprise transimpedance amplifiers. These transimpedance amplifiers may be configured to match one or more photodiodes in a detector based on a noise model that accounts for characteristics, such as the impedance, of the transimpedance amplifier, characteristics of each photodiode, such as the impedance, and the number of photodiodes coupled to the transimpedance amplifier.

[0065] In the present disclosure, the front-ends are employed in a sensor that measures various blood analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes, such as glucose, total hemoglobin, methemoglobin, oxygen content, and the like, based on various combinations of features and components.

[0066] In an embodiment, a physiological sensor includes a detector housing that can be coupled to a measurement site, such as a patient's finger. The sensor housing can include a curved bed that can generally conform to the shape of the measurement site. In addition, the curved bed can include a protrusion shaped

to increase an amount of light radiation from the measurement site. In an embodiment, the protrusion is used to thin out the measurement site. This allows the light radiation to pass through less tissue, and accordingly is attenuated less. In an embodiment, the protrusion can be used to increase the area from which attenuated light can be measured. In an embodiment, this is done through the use of a lens which collects attenuated light exiting the measurement site and focuses onto one or more detectors. The protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic, helpful in reducing light noise. In an embodiment, such light noise includes light that would otherwise be detected at a photodetector that has not been attenuated by tissue of the measurement site of a patient sufficient to cause the light to adequately included information indicative of one or more physiological parameters of the patient. Such light noise includes light piping.

[0067] In an embodiment, the protrusion can be formed from the curved bed, or can be a separate component that is positionable with respect to the bed. In an embodiment, a lens made from any appropriate material is used as the protrusion. The protrusion can be convex in shape. The protrusion can also be sized and shaped to conform the measurement site into a flat or relatively flat surface. The protrusion can also be sized to conform the measurement site into a rounded surface, such as, for example, a concave or convex surface. The protrusion can include a cylindrical or partially cylindrical shape. The protrusion can be sized or shaped differently for different types of patients, such as an adult, child, or infant. The protrusion can also be sized or shaped differently for different measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like. The protrusion can thus be helpful in any type of noninvasive sensor. The external surface of the protrusion can include one or more openings or windows. The openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors. Alternatively, some of all of the protrusion can be a lens, such as a partially cylindrical lens.

[0068] The sensor can also include a shielding, such as a metal enclosure as described below or embedded within the protrusion to reduce noise. The shielding can be constructed from a conductive material, such as copper, in the form of a metal cage or enclosure, such as a box. The shielding can include a second set of one or more openings or windows. The second set of openings can be made from glass and allow light that has passed through the first set of windows of the external surface of the protrusion to pass through to one or more detectors that can be enclosed, for example, as described below.

[0069] In various embodiments, the shielding can include any substantially transparent, conductive material placed in the optical path between an emitter and a detector. The shielding can be constructed from a transparent material, such as glass, plastic, and the like. The shielding can have an electrically conductive material or coating that is at least partially transparent. The electrically conductive coating can be located on one or both sides of the shielding, or within the body of the shielding. In addition, the electrically conductive coating can be uniformly spread over the shielding or may be patterned. Furthermore, the coating can have a uniform or varying thickness to increase or optimize its shielding effect. The shielding can be helpful in virtually any type of noninvasive sensor that employs spectroscopy.

[0070] In an embodiment, the sensor can also include a heat sink. In an embodiment, the heat sink can include a shape that is functional in its ability to dissipate excess heat and aesthetically pleasing to the wearer. For example, the heat sink can be configured in a shape that maximizes surface area to allow for greater dissipation of heat. In an embodiment, the heat sink includes a metalized plastic, such as plastic including carbon and aluminum to allow for improved thermal conductivity and diffusivity. In an embodiment, the heat sink can advantageously be inexpensively molded into desired shapes and configurations for aesthetic and functional purposes. For example, the shape of the heat sink can be a generally curved surface and include one or more fins, undulations, grooves or channels, or combs.

[0071] The sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter can include a plurality of sets of optical sources that, in an embodiment, are arranged together as a point source. The various optical sources can emit a sequence of optical radiation pulses at different wavelengths towards a measurement site, such as a patient's finger. Detectors can then detect optical radiation from the measurement site. The optical sources and optical radiation detectors can operate at any appropriate wavelength, including, as discussed herein, infrared, near infrared, visible light, and ultraviolet. In addition, the optical sources and optical radiation detectors can operate at any appropriate wavelength, and such modifications to the embodiments desirable to operate at any such wavelength will be apparent to those skilled in the art.

[0072] In certain embodiments, multiple detectors are employed and arranged in a spatial geometry. This spatial geometry provides a diversity of path lengths among at least some of the detectors and allows for multiple bulk and pulsatile measurements that are robust. Each of the detectors can provide a respective output stream based on the detected optical radiation, or a sum of output streams can be provided from multiple detectors. In some embodiments, the sensor can also include other components, such as one or more heat sinks and one or more thermistors.

[0073] The spatial configuration of the detectors provides a geometry having a diversity of path lengths among the detectors. For example, a detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction. In addition, walls may be used to separate individual photodetectors and prevent mixing of detected optical radiation between the different locations on the measurement site. A window may also be employed to facilitate the passing of optical radiation at various wavelengths for measuring glucose in the tissue.

[0074] In the present disclosure, a sensor may measure various blood constituents or analytes noninvasively using spectroscopy and a recipe of various features. As disclosed herein, the sensor is capable of non-invasively measuring blood analytes, such as, glucose, total hemoglobin, methemoglobin, oxygen content,

and the like. In an embodiment, the spectroscopy used in the sensor can employ visible, infrared and near infrared wavelengths. The sensor may comprise an emitter, a detector, and other components. In some embodiments, the sensor may also comprise other components, such as one or more heat sinks and one or more thermistors.

[0075] In various embodiments, the sensor may also be coupled to one or more companion devices that process and/or display the sensor's output. The companion devices may comprise various components, such as a sensor front-end, a signal processor, a display, a network interface, a storage device or memory, etc.

[0076] A sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter is configured as a point optical source that comprises a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In some embodiments, the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED. In some embodiments, the emitter comprises optical sources that transmit optical radiation in the infrared or near-infrared wavelengths suitable for detecting blood analytes like glucose. In order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. In addition, the emitter may have its duty cycle modified to achieve a desired SNR.

[0077] The emitter may be constructed of materials, such as aluminum nitride and may include a heat sink to assist in heat dissipation. A thermistor may also be employed to account for heating effects on the LEDs. The emitter may further comprise a glass window and a nitrogen environment to improve transmission from the sources and prevent oxidative effects.

[0078] The sensor can be coupled to one or more monitors that process and/or display the sensor's output. The monitors can include various components, such as a sensor front end, a signal processor, a display, etc.

[0079] The sensor can be integrated with a monitor, for example, into a handheld unit including the sensor, a display and user controls. In other embodiments, the sensor can communicate with one or more processing devices.

The communication can be via wire(s), cable(s), flex circuit(s), wireless technologies, or other suitable analog or digital communication methodologies and devices to perform those methodologies. Many of the foregoing arrangements allow the sensor to be attached to the measurement site while the device is attached elsewhere on a patient, such as the patient's arm, or placed at a location near the patient, such as a bed, shelf or table. The sensor or monitor can also provide outputs to a storage device or network interface.

[0080] Reference will now be made to the Figures to discuss embodiments of the present disclosure.

[0081] FIGURE 1 illustrates an example of a data collection system 100. In certain embodiments, the data collection system 100 noninvasively measure a blood analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. The system 100 can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

[0082] The data collection system 100 can be capable of measuring optical radiation from the measurement site. For example, in some embodiments, the data collection system 100 can employ photodiodes defined in terms of area. In an embodiment, the area is from about 1 mm^2 – 5 mm^2 (or higher) that are capable of detecting about 100 nanoamps (nA) or less of current resulting from measured light at full scale. In addition to having its ordinary meaning, the phrase “at full scale” can mean light saturation of a photodiode amplifier (not shown). Of course, as would be understood by a person of skill in the art from the present disclosure, various other sizes and types of photodiodes can be used with the embodiments of the present disclosure.

[0083] The data collection system 100 can measure a range of approximately about 2 nA to about 100 nA full scale. The data collection system 100 can also include sensor front-ends that are capable of processing and amplifying current from the detector(s) at signal-to-noise ratios (SNRs) of about 100 decibels (dB) or more, such as about 120 dB in order to measure various desired

analytes. The data collection system 100 can operate with a lower SNR if less accuracy is desired for an analyte like glucose.

[0084] The data collection system 100 can measure analyte concentrations, including glucose, at least in part by detecting light attenuated by a measurement site 102. The measurement site 102 can be any location on a patient's body, such as a finger, foot, ear lobe, or the like. For convenience, this disclosure is described primarily in the context of a finger measurement site 102. However, the features of the embodiments disclosed herein can be used with other measurement sites 102.

[0085] In the depicted embodiment, the system 100 includes an optional tissue thickness adjuster or tissue shaper 105, which can include one or more protrusions, bumps, lenses, or other suitable tissue-shaping mechanisms. In certain embodiments, the tissue shaper 105 is a flat or substantially flat surface that can be positioned proximate the measurement site 102 and that can apply sufficient pressure to cause the tissue of the measurement site 102 to be flat or substantially flat. In other embodiments, the tissue shaper 105 is a convex or substantially convex surface with respect to the measurement site 102. Many other configurations of the tissue shaper 105 are possible. Advantageously, in certain embodiments, the tissue shaper 105 reduces thickness of the measurement site 102 while preventing or reducing occlusion at the measurement site 102. Reducing thickness of the site can advantageously reduce the amount of attenuation of the light because there is less tissue through which the light must travel. Shaping the tissue in to a convex (or alternatively concave) surface can also provide more surface area from which light can be detected.

[0086] The embodiment of the data collection system 100 shown also includes an optional noise shield 103. In an embodiment, the noise shield 103 can be advantageously adapted to reduce electromagnetic noise while increasing the transmittance of light from the measurement site 102 to one or more detectors 106 (described below). For example, the noise shield 103 can advantageously include a conductive coated glass or metal grid electrically communicating with one or more other shields of the sensor 101 or electrically grounded. In an embodiment where

the noise shield 103 includes conductive coated glass, the coating can advantageously include indium tin oxide. In an embodiment, the indium tin oxide includes a surface resistivity ranging from approximately 30 ohms per square inch to about 500 ohms per square inch. In an embodiment, the resistivity is approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than about 30 ohms or more than about 500 ohms. Other conductive materials transparent or substantially transparent to light can be used instead.

[0087] In some embodiments, the measurement site 102 is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person's left arm or left hand. In some patients, the non-dominant arm or hand can have less musculature and higher fat content, which can result in less water content in that tissue of the patient. Tissue having less water content can provide less interference with the particular wavelengths that are absorbed in a useful manner by blood analytes like glucose. Accordingly, in some embodiments, the data collection system 100 can be used on a person's non-dominant hand or arm.

[0088] The data collection system 100 can include a sensor 101 (or multiple sensors) that is coupled to a processing device or physiological monitor 109. In an embodiment, the sensor 101 and the monitor 109 are integrated together into a single unit. In another embodiment, the sensor 101 and the monitor 109 are separate from each other and communicate one with another in any suitable manner, such as via a wired or wireless connection. The sensor 101 and monitor 109 can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like. The sensor 101 and the monitor 109 will now be further described.

[0089] In the depicted embodiment shown in **FIGURE 1**, the sensor 101 includes an emitter 104, a tissue shaper 105, a set of detectors 106, and a front-end interface 108. The emitter 104 can serve as the source of optical radiation transmitted towards measurement site 102. As will be described in further detail below, the emitter 104 can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters,

combinations of the same, or the like. In an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

[0090] In some embodiments, the emitter 104 is used as a point optical source, and thus, the one or more optical sources of the emitter 104 can be located within a close distance to each other, such as within about a 2 mm to about 4 mm. The emitters 104 can be arranged in an array, such as is described in U.S. Publication No. 2006/0211924, filed Sept. 21, 2006, titled "Multiple Wavelength Sensor Emitters," the disclosure of which is hereby incorporated by reference in its entirety. In particular, the emitters 104 can be arranged at least in part as described in paragraphs [0061] through [0068] of the aforementioned publication, which paragraphs are hereby incorporated specifically by reference. Other relative spatial relationships can be used to arrange the emitters 104.

[0091] For analytes like glucose, currently available non-invasive techniques often attempt to employ light near the water absorbance minima at or about 1600 nm. Typically, these devices and methods employ a single wavelength or single band of wavelengths at or about 1600 nm. However, to date, these techniques have been unable to adequately consistently measure analytes like glucose based on spectroscopy.

[0092] In contrast, the emitter 104 of the data collection system 100 can emit, in certain embodiments, combinations of optical radiation in various bands of interest. For example, in some embodiments, for analytes like glucose, the emitter 104 can emit optical radiation at three (3) or more wavelengths between about 1600 nm to about 1700 nm. In particular, the emitter 104 can emit optical radiation at or about 1610 nm, about 1640 nm, and about 1665 nm. In some circumstances, the use of three wavelengths within about 1600 nm to about 1700 nm enable sufficient SNRs of about 100 dB, which can result in a measurement accuracy of about 20 mg/dL or better for analytes like glucose.

[0093] In other embodiments, the emitter 104 can use two (2) wavelengths within about 1600 nm to about 1700 nm to advantageously enable SNRs of about 85 dB, which can result in a measurement accuracy of about 25-30 mg/dL or better

for analytes like glucose. Furthermore, in some embodiments, the emitter 104 can emit light at wavelengths above about 1670 nm. Measurements at these wavelengths can be advantageously used to compensate or confirm the contribution of protein, water, and other non-hemoglobin species exhibited in measurements for analytes like glucose conducted between about 1600 nm and about 1700 nm. Of course, other wavelengths and combinations of wavelengths can be used to measure analytes and/or to distinguish other types of tissue, fluids, tissue properties, fluid properties, combinations of the same or the like.

[0094] For example, the emitter 104 can emit optical radiation across other spectra for other analytes. In particular, the emitter 104 can employ light wavelengths to measure various blood analytes or percentages (e.g., saturation) thereof. For example, in one embodiment, the emitter 104 can emit optical radiation in the form of pulses at wavelengths about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter 104 can emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, the emitter 104 can transmit any of a variety of wavelengths of visible or near-infrared optical radiation.

[0095] Due to the different responses of analytes to the different wavelengths, certain embodiments of the data collection system 100 can advantageously use the measurements at these different wavelengths to improve the accuracy of measurements. For example, the measurements of water from visible and infrared light can be used to compensate for water absorbance that is exhibited in the near-infrared wavelengths.

[0096] As briefly described above, the emitter 104 can include sets of light-emitting diodes (LEDs) as its optical source. The emitter 104 can use one or more top-emitting LEDs. In particular, in some embodiments, the emitter 104 can include top-emitting LEDs emitting light at about 850 nm to 1350 nm.

[0097] The emitter 104 can also use super luminescent LEDs (SLEDs) or side-emitting LEDs. In some embodiments, the emitter 104 can employ SLEDs or

side-emitting LEDs to emit optical radiation at about 1600 nm to about 1800 nm. Emitter 104 can use SLEDs or side-emitting LEDs to transmit near infrared optical radiation because these types of sources can transmit at high power or relatively high power, e.g., about 40 mW to about 100 mW. This higher power capability can be useful to compensate or overcome the greater attenuation of these wavelengths of light in tissue and water. For example, the higher power emission can effectively compensate and/or normalize the absorption signal for light in the mentioned wavelengths to be similar in amplitude and/or effect as other wavelengths that can be detected by one or more photodetectors after absorption. However, the embodiments of the present disclosure do not necessarily require the use of high power optical sources. For example, some embodiments may be configured to measure analytes, such as total hemoglobin (tHb), oxygen saturation (SpO₂), carboxyhemoglobin, methemoglobin, etc., without the use of high power optical sources like side emitting LEDs. Instead, such embodiments may employ other types of optical sources, such as top emitting LEDs. Alternatively, the emitter 104 can use other types of sources of optical radiation, such as a laser diode, to emit near-infrared light into the measurement site 102.

[0098] In addition, in some embodiments, in order to assist in achieving a comparative balance of desired power output between the LEDs, some of the LEDs in the emitter 104 can have a filter or covering that reduces and/or cleans the optical radiation from particular LEDs or groups of LEDs. For example, since some wavelengths of light can penetrate through tissue relatively well, LEDs, such as some or all of the top-emitting LEDs can use a filter or covering, such as a cap or painted dye. This can be useful in allowing the emitter 104 to use LEDs with a higher output and/or to equalize intensity of LEDs.

[0099] The data collection system 100 also includes a driver 111 that drives the emitter 104. The driver 111 can be a circuit or the like that is controlled by the monitor 109. For example, the driver 111 can provide pulses of current to the emitter 104. In an embodiment, the driver 111 drives the emitter 104 in a progressive fashion, such as in an alternating manner. The driver 111 can drive the emitter 104 with a series of pulses of about 1 milliwatt (mW) for some wavelengths

that can penetrate tissue relatively well and from about 40 mW to about 100 mW for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments.

[0100] The driver 111 can be synchronized with other parts of the sensor 101 and can minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter 104. In some embodiments, the driver 111 is capable of driving the emitter 104 to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

[0101] The detectors 106 capture and measure light from the measurement site 102. For example, the detectors 106 can capture and measure light transmitted from the emitter 104 that has been attenuated or reflected from the tissue in the measurement site 102. The detectors 106 can output a detector signal 107 responsive to the light captured or measured. The detectors 106 can be implemented using one or more photodiodes, phototransistors, or the like.

[0102] In addition, the detectors 106 can be arranged with a spatial configuration to provide a variation of path lengths among at least some of the detectors 106. That is, some of the detectors 106 can have the substantially, or from the perspective of the processing algorithm, effectively, the same path length from the emitter 104. However, according to an embodiment, at least some of the detectors 106 can have a different path length from the emitter 104 relative to other of the detectors 106. Variations in path lengths can be helpful in allowing the use of a bulk signal stream from the detectors 106. In some embodiments, the detectors 106 may employ a linear spacing, a logarithmic spacing, or a two or three dimensional matrix of spacing, or any other spacing scheme in order to provide an appropriate variation in path lengths.

[0103] The front end interface 108 provides an interface that adapts the output of the detectors 106, which is responsive to desired physiological parameters. For example, the front end interface 108 can adapt a signal 107 received from one or more of the detectors 106 into a form that can be processed by the monitor 109, for example, by a signal processor 110 in the monitor 109. The

front end interface 108 can have its components assembled in the sensor 101, in the monitor 109, in connecting cabling (if used), combinations of the same, or the like. The location of the front end interface 108 can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

[0104] The front end interface 108 can be coupled to the detectors 106 and to the signal processor 110 using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front end interface 108 can also be at least partially integrated with various components, such as the detectors 106. For example, the front end interface 108 can include one or more integrated circuits that are on the same circuit board as the detectors 106. Other configurations can also be used.

[0105] The front end interface 108 can be implemented using one or more amplifiers, such as transimpedance amplifiers, that are coupled to one or more analog to digital converters (ADCs) (which can be in the monitor 109), such as a sigma-delta ADC. A transimpedance-based front end interface 108 can employ single-ended circuitry, differential circuitry, and/or a hybrid configuration. A transimpedance-based front end interface 108 can be useful for its sampling rate capability and freedom in modulation/demodulation algorithms. For example, this type of front end interface 108 can advantageously facilitate the sampling of the ADCs being synchronized with the pulses emitted from the emitter 104.

[0106] The ADC or ADCs can provide one or more outputs into multiple channels of digital information for processing by the signal processor 110 of the monitor 109. Each channel can correspond to a signal output from a detector 106.

[0107] In some embodiments, a programmable gain amplifier (PGA) can be used in combination with a transimpedance-based front end interface 108. For example, the output of a transimpedance-based front end interface 108 can be output to a PGA that is coupled with an ADC in the monitor 109. A PGA can be useful in order to provide another level of amplification and control of the stream of signals from the detectors 106. Alternatively, the PGA and ADC components can

be integrated with the transimpedance-based front end interface 108 in the sensor 101.

[0108] In another embodiment, the front end interface 108 can be implemented using switched-capacitor circuits. A switched-capacitor-based front end interface 108 can be useful for, in certain embodiments, its resistor-free design and analog averaging properties. In addition, a switched-capacitor-based front end interface 108 can be useful because it can provide a digital signal to the signal processor 110 in the monitor 109.

[0109] As shown in **FIGURE 1**, the monitor 109 can include the signal processor 110 and a user interface, such as a display 112. The monitor 109 can also include optional outputs alone or in combination with the display 112, such as a storage device 114 and a network interface 116. In an embodiment, the signal processor 110 includes processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors 106. The signal processor 110 can be implemented using one or more microprocessors or subprocessors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

[0110] The signal processor 110 can provide various signals that control the operation of the sensor 101. For example, the signal processor 110 can provide an emitter control signal to the driver 111. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter 104. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter 104 to follow a precise timing and consistent pattern. For example, when a transimpedance-based front end interface 108 is used, the control signal from the signal processor 110 can provide synchronization with the ADC in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory 113 can be included in the front-end interface 108 and/or in the signal processor 110. This memory 113 can serve as a buffer or storage location for the front-end interface 108 and/or the signal processor 110, among other uses.

[0111] The user interface 112 can provide an output, e.g., on a display, for presentation to a user of the data collection system 100. The user interface 112 can be implemented as a touch-screen display, an LCD display, an organic LED display, or the like. In addition, the user interface 112 can be manipulated to allow for measurement on the non-dominant side of patient. For example, the user interface 112 can include a flip screen, a screen that can be moved from one side to another on the monitor 109, or can include an ability to reorient its display indicia responsive to user input or device orientation. In alternative embodiments, the data collection system 100 can be provided without a user interface 112 and can simply provide an output signal to a separate display or system.

[0112] A storage device 114 and a network interface 116 represent other optional output connections that can be included in the monitor 109. The storage device 114 can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device 114, which can be executed by the signal processor 110 or another processor of the monitor 109. The network interface 116 can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor 109 to communicate and share data with other devices. The monitor 109 can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface 112, to control data communications, to compute data trending, or to perform other operations.

[0113] Although not shown in the depicted embodiment, the data collection system 100 can include various other components or can be configured in different ways. For example, the sensor 101 can have both the emitter 104 and detectors 106 on the same side of the measurement site 102 and use reflectance to measure analytes. The data collection system 100 can also include a sensor that measures the power of light emitted from the emitter 104.

[0114] **FIGURES 2A** through **2D** illustrate example monitoring devices 200 in which the data collection system 100 can be housed. Advantageously, in certain embodiments, some or all of the example monitoring devices 200 shown can have a shape and size that allows a user to operate it with a single hand or attach it, for example, to a patient's body or limb. Although several examples are shown, many other monitoring device configurations can be used to house the data collection system 100. In addition, certain of the features of the monitoring devices 200 shown in **FIGURES 2A** through **2D** can be combined with features of the other monitoring devices 200 shown.

[0115] Referring specifically to **FIGURE 2A**, an example monitoring device 200A is shown, in which a sensor 201a and a monitor 209a are integrated into a single unit. The monitoring device 200A shown is a handheld or portable device that can measure glucose and other analytes in a patient's finger. The sensor 201a includes an emitter shell 204a and a detector shell 206a. The depicted embodiment of the monitoring device 200A also includes various control buttons 208a and a display 210a.

[0116] The sensor 201a can be constructed of white material used for reflective purposes (such as white silicone or plastic), which can increase the usable signal at the detector 106 by forcing light back into the sensor 201a. Pads in the emitter shell 204a and the detector shell 206a can contain separated windows to prevent or reduce mixing of light signals, for example, from distinct quadrants on a patient's finger. In addition, these pads can be made of a relatively soft material, such as a gel or foam, in order to conform to the shape, for example, of a patient's finger. The emitter shell 204a and the detector shell 206a can also include absorbing black or grey material portions to prevent or reduce ambient light from entering into the sensor 201a.

[0117] In some embodiments, some or all portions of the emitter shell 204a and/or detector shell 206a can be detachable and/or disposable. For example, some or all portions of the shells 204a and 206a can be removable pieces. The removability of the shells 204a and 206a can be useful for sanitary purposes or for sizing the sensor 201a to different patients. The monitor 209a can include a

fitting, slot, magnet, or other connecting mechanism to allow the sensor 201c to be removably attached to the monitor 209a.

[0118] The monitoring device 200a also includes optional control buttons 208a and a display 210a that can allow the user to control the operation of the device. For example, a user can operate the control buttons 208a to view one or more measurements of various analytes, such as glucose. In addition, the user can operate the control buttons 208a to view other forms of information, such as graphs, histograms, measurement data, trend measurement data, parameter combination views, wellness indications, and the like. Many parameters, trends, alarms and parameter displays could be output to the display 210a, such as those that are commercially available through a wide variety of noninvasive monitoring devices from Masimo[®] Corporation of Irvine, California.

[0119] Furthermore, the controls 208a and/or display 210a can provide functionality for the user to manipulate settings of the monitoring device 200a, such as alarm settings, emitter settings, detector settings, and the like. The monitoring device 200a can employ any of a variety of user interface designs, such as frames, menus, touch-screens, and any type of button.

[0120] **FIGURE 2B** illustrates another example of a monitoring device 200B. In the depicted embodiment, the monitoring device 200B includes a finger clip sensor 201b connected to a monitor 209b via a cable 212. In the embodiment shown, the monitor 209b includes a display 210b, control buttons 208b and a power button. Moreover, the monitor 209b can advantageously include electronic processing, signal processing, and data storage devices capable of receiving signal data from said sensor 201b, processing the signal data to determine one or more output measurement values indicative of one or more physiological parameters of a monitored patient, and displaying the measurement values, trends of the measurement values, combinations of measurement values, and the like.

[0121] The cable 212 connecting the sensor 201b and the monitor 209b can be implemented using one or more wires, optical fiber, flex circuits, or the like. In some embodiments, the cable 212 can employ twisted pairs of conductors in order to minimize or reduce cross-talk of data transmitted from the sensor 201b to

the monitor 209b. Various lengths of the cable 212 can be employed to allow for separation between the sensor 201b and the monitor 209b. The cable 212 can be fitted with a connector (male or female) on either end of the cable 212 so that the sensor 201b and the monitor 209b can be connected and disconnected from each other. Alternatively, the sensor 201b and the monitor 209b can be coupled together via a wireless communication link, such as an infrared link, radio frequency channel, or any other wireless communication protocol and channel.

[0122] The monitor 209b can be attached to the patient. For example, the monitor 209b can include a belt clip or straps (see, e.g., FIGURE 2C) that facilitate attachment to a patient's belt, arm, leg, or the like. The monitor 209b can also include a fitting, slot, magnet, LEMO snap-click connector, or other connecting mechanism to allow the cable 212 and sensor 201b to be attached to the monitor 209B.

[0123] The monitor 209b can also include other components, such as a speaker, power button, removable storage or memory (e.g., a flash card slot), an AC power port, and one or more network interfaces, such as a universal serial bus interface or an Ethernet port. For example, the monitor 209b can include a display 210b that can indicate a measurement for glucose, for example, in mg/dL. Other analytes and forms of display can also appear on the monitor 209b.

[0124] In addition, although a single sensor 201b with a single monitor 209b is shown, different combinations of sensors and device pairings can be implemented. For example, multiple sensors can be provided for a plurality of differing patient types or measurement sites or even patient fingers.

[0125] **FIGURE 2C** illustrates yet another example of monitoring device 200C that can house the data collection system 100. Like the monitoring device 200B, the monitoring device 200C includes a finger clip sensor 201c connected to a monitor 209c via a cable 212. The cable 212 can have all of the features described above with respect to FIGURE 2B. The monitor 209c can include all of the features of the monitor 200B described above. For example, the monitor 209c includes buttons 208c and a display 210c. The monitor 209c shown also includes straps 214c that allow the monitor 209c to be attached to a patient's limb or the like.

[0126] FIGURE 2D illustrates yet another example of monitoring device 200D that can house the data collection system 100. Like the monitoring devices 200B and 200C, the monitoring device 200D includes a finger clip sensor 201d connected to a monitor 209d via a cable 212. The cable 212 can have all of the features described above with respect to FIGURE 2B. In addition to having some or all of the features described above with respect to FIGURES 2B and 2C, the monitoring device 200D includes an optional universal serial bus (USB) port 216 and an Ethernet port 218. The USB port 216 and the Ethernet port 218 can be used, for example, to transfer information between the monitor 209d and a computer (not shown) via a cable. Software stored on the computer can provide functionality for a user to, for example, view physiological data and trends, adjust settings and download firmware updates to the monitor 209b, and perform a variety of other functions. The USB port 216 and the Ethernet port 218 can be included with the other monitoring devices 200A, 200B, and 200C described above.

[0127] FIGURES 3A through 3C illustrate more detailed examples of embodiments of a sensor 301a. The sensor 301a shown can include all of the features of the sensors 100 and 200 described above.

[0128] Referring to **FIGURE 3A**, the sensor 301a in the depicted embodiment is a clothespin-shaped clip sensor that includes an enclosure 302a for receiving a patient's finger. The enclosure 302a is formed by an upper section or emitter shell 304a, which is pivotably connected with a lower section or detector shell 306a. The emitter shell 304a can be biased with the detector shell 306a to close together around a pivot point 303a and thereby sandwich finger tissue between the emitter and detector shells 304a, 306a.

[0129] In an embodiment, the pivot point 303a advantageously includes a pivot capable of adjusting the relationship between the emitter and detector shells 304a, 306a to effectively level the sections when applied to a tissue site. In another embodiment, the sensor 301a includes some or all features of the finger clip described in U.S. Publication No. 2006/0211924, incorporated above, such as a spring that causes finger clip forces to be distributed along the finger. Paragraphs

[0096] through [0105], which describe this feature, are hereby specifically incorporated by reference.

[0130] The emitter shell 304a can position and house various emitter components of the sensor 301a. It can be constructed of reflective material (e.g., white silicone or plastic) and/or can be metallic or include metalized plastic (e.g., including carbon and aluminum) to possibly serve as a heat sink. The emitter shell 304a can also include absorbing opaque material, such as, for example, black or grey colored material, at various areas, such as on one or more flaps 307a, to reduce ambient light entering the sensor 301a.

[0131] The detector shell 306a can position and house one or more detector portions of the sensor 301a. The detector shell 306a can be constructed of reflective material, such as white silicone or plastic. As noted, such materials can increase the usable signal at a detector by forcing light back into the tissue and measurement site (see FIGURE 1). The detector shell 306a can also include absorbing opaque material at various areas, such as lower area 308a, to reduce ambient light entering the sensor 301a.

[0132] Referring to **FIGURES 3B** and **3C**, an example of finger bed 310 is shown in the sensor 301b. The finger bed 310 includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed 310 includes one or more ridges or channels 314. Each of the ridges 314 has a generally convex shape that can facilitate increasing traction or gripping of the patient's finger to the finger bed. Advantageously, the ridges 314 can improve the accuracy of spectroscopic analysis in certain embodiments by reducing noise that can result from a measurement site moving or shaking loose inside of the sensor 301a. The ridges 314 can be made from reflective or opaque materials in some embodiments to further increase SNR. In other implementations, other surface shapes can be used, such as, for example, generally flat, concave, or convex finger beds 310.

[0133] Finger bed 310 can also include an embodiment of a tissue thickness adjuster or protrusion 305. The protrusion 305 includes a measurement site contact area 370 (see FIGURE 3C) that can contact body tissue of a

measurement site. The protrusion 305 can be removed from or integrated with the finger bed 310. Interchangeable, different shaped protrusions 305 can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

[0134] Referring specifically to **FIGURE 3C**, the contact area 370 of the protrusion 305 can include openings or windows 320, 321, 322, and 323. When light from a measurement site passes through the windows 320, 321, 322, and 323, the light can reach one or more photodetectors (see FIGURE 3E). In an embodiment, the windows 320, 321, 322, and 323 mirror specific detector placements layouts such that light can impinge through the protrusion 305 onto the photodetectors. Any number of windows 320, 321, 322, and 323 can be employed in the protrusion 305 to allow light to pass from the measurement site to the photodetectors.

[0135] The windows 320, 321, 322, and 323 can also include shielding, such as an embedded grid of wiring or a conductive glass coating, to reduce noise from ambient light or other electromagnetic noise. The windows 320, 321, 322, and 323 can be made from materials, such as plastic or glass. In some embodiments, the windows 320, 321, 322, and 323 can be constructed from conductive glass, such as indium tin oxide (ITO) coated glass. Conductive glass can be useful because its shielding is transparent, and thus allows for a larger aperture versus a window with an embedded grid of wiring. In addition, in certain embodiments, the conductive glass does not need openings in its shielding (since it is transparent), which enhances its shielding performance. For example, some embodiments that employ the conductive glass can attain up to an about 40% to about 50% greater signal than non-conductive glass with a shielding grid. In addition, in some embodiments, conductive glass can be useful for shielding noise from a greater variety of directions than non-conductive glass with a shielding grid.

[0136] Turning to **FIGURE 3B**, the sensor 301a can also include a shielding 315a, such as a metal cage, box, metal sheet, perforated metal sheet, a metal layer on a non-metal material, or the like. The shielding 315a is provided in the depicted embodiment below or embedded within the protrusion 305 to reduce

noise. The shielding 315a can be constructed from a conductive material, such as copper. The shielding 315a can include one or more openings or windows (not shown). The windows can be made from glass or plastic to thereby allow light that has passed through the windows 320, 321, 322, and 323 on an external surface of the protrusion 305 (see FIGURE 3C) to pass through to one or more photodetectors that can be enclosed or provided below (see FIGURE 3E).

[0137] In some embodiments, the shielding cage for shielding 315a can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding cage can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

[0138] In an embodiment, the photodetectors can be positioned within or directly beneath the protrusion 305 (see FIGURE 3E). In such cases, the mean optical path length from the emitters to the detectors can be reduced and the accuracy of blood analyte measurement can increase. For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm² to about 60 mm² was found to help signal strength by about an order of magnitude versus other shapes. Of course other dimensions and sizes can be employed in other embodiments. Depending on the properties desired, the length, width, and height of the protrusion 305 can be selected. In making such determinations, consideration can be made of protrusion's 305 effect on blood flow at the measurement site and mean path length for optical radiation passing through openings 320, 321, 322, and 323. Patient comfort can also be considered in determining the size and shape of the protrusion.

[0139] In an embodiment, the protrusion 305 can include a pliant material, including soft plastic or rubber, which can somewhat conform to the shape of a measurement site. Pliant materials can improve patient comfort and tactility by conforming the measurement site contact area 370 to the measurement site. Additionally, pliant materials can minimize or reduce noise, such as ambient light.

Alternatively, the protrusion 305 can be made from a rigid material, such as hard plastic or metal.

[0140] Rigid materials can improve measurement accuracy of a blood analyte by conforming the measurement site to the contact area 370. The contact area 370 can be an ideal shape for improving accuracy or reducing noise. Selecting a material for the protrusion 305 can include consideration of materials that do not significantly alter blood flow at the measurement site. The protrusion 305 and the contact area 370 can include a combination of materials with various characteristics.

[0141] The contact area 370 serves as a contact surface for the measurement site. For example, in some embodiments, the contact area 370 can be shaped for contact with a patient's finger. Accordingly, the contact area 370 can be sized and shaped for different sizes of fingers. The contact area 370 can be constructed of different materials for reflective purposes as well as for the comfort of the patient. For example, the contact area 370 can be constructed from materials having various hardness and textures, such as plastic, gel, foam, and the like.

[0142] The formulas and analysis that follow with respect to **FIGURE 5** provide insight into how selecting these variables can alter transmittance and intensity gain of optical radiation that has been applied to the measurement site. These examples do not limit the scope of this disclosure.

[0143] Referring to **FIGURE 5**, a plot 500 is shown that illustrates examples of effects of embodiments of the protrusion 305 on the SNR at various wavelengths of light. As described above, the protrusion 305 can assist in conforming the tissue and effectively reduce its mean path length. In some instances, this effect by the protrusion 305 can have significant impact on increasing the SNR.

[0144] According to the Beer Lambert law, a transmittance of light (I) can be expressed as follows: $I = I_0 * e^{-m*b*c}$, where I_0 is the initial power of light being transmitted, m is the path length traveled by the light, and the component " $b*c$ " corresponds to the bulk absorption of the light at a specific wavelength of light. For light at about 1600 nm to about 1700 nm, for example, the bulk absorption component is generally around 0.7 mm^{-1} . Assuming a typical finger thickness of

about 12 mm and a mean path length of 20 mm due to tissue scattering, then $I = I_0 * e^{(-20*0.7)}$.

[0145] In an embodiment where the protrusion 305 is a convex bump, the thickness of the finger can be reduced to 10 mm (from 12 mm) for some fingers and the effective light mean path is reduced to about 16.6 mm from 20 mm (see box 510). This results in a new transmittance, $I_1 = I_0 * e^{(-16.6*0.7)}$. A curve for a typical finger (having a mean path length of 20 mm) across various wavelengths is shown in the plot 500 of **FIGURE 5**. The plot 500 illustrates potential effects of the protrusion 305 on the transmittance. As illustrated, comparing I and I_1 results in an intensity gain of $e^{(-16.6*0.7)}/e^{(-20*0.7)}$, which is about a 10 times increase for light in the about 1600 nm to about 1700 nm range. Such an increase can affect the SNR at which the sensor can operate. The foregoing gains can be due at least in part to the about 1600 nm to about 1700 nm range having high values in bulk absorptions (water, protein, and the like), e.g., about 0.7 mm^{-1} . The plot 500 also shows improvements in the visible/near-infrared range (about 600 nm to about 1300 nm).

[0146] Turning again to **FIGURES 3A** through **3C**, an example heat sink 350a is also shown. The heat sink 350a can be attached to, or protrude from an outer surface of, the sensor 301a, thereby providing increased ability for various sensor components to dissipate excess heat. By being on the outer surface of the sensor 301a in certain embodiments, the heat sink 350a can be exposed to the air and thereby facilitate more efficient cooling. In an embodiment, one or more of the emitters (see **FIGURE 1**) generate sufficient heat that inclusion of the heat sink 350a can advantageously allows the sensor 301a to remain safely cooled. The heat sink 350a can include one or more materials that help dissipate heat, such as, for example, aluminum, steel, copper, carbon, combinations of the same, or the like. For example, in some embodiments, the emitter shell 304a can include a heat conducting material that is also readily and relatively inexpensively moldable into desired shapes and forms.

[0147] In some embodiments, the heat sink 350a includes metalicized plastic. The metalicized plastic can include aluminum and carbon, for example. The material can allow for improved thermal conductivity and diffusivity, which can

increase commercial viability of the heat sink. In some embodiments, the material selected to construct the heat sink 350a can include a thermally conductive liquid crystalline polymer, such as CoolPoly[®] D5506, commercially available from Cool Polymers[®], Inc. of Warwick, Rhode Island. Such a material can be selected for its electrically non-conductive and dielectric properties so as, for example, to aid in electrical shielding. In an embodiment, the heat sink 350a provides improved heat transfer properties when the sensor 301a is active for short intervals of less than a full day's use. In an embodiment, the heat sink 350a can advantageously provide improved heat transfers in about three (3) to about four (4) minute intervals, for example, although a heat sink 350a can be selected that performs effectively in shorter or longer intervals.

[0148] Moreover, the heat sink 350a can have different shapes and configurations for aesthetic as well as for functional purposes. In an embodiment, the heat sink is configured to maximize heat dissipation, for example, by maximizing surface area. In an embodiment, the heat sink 350a is molded into a generally curved surface and includes one or more fins, undulations, grooves, or channels. The example heat sink 350a shown includes fins 351a (see FIGURE 3A).

[0149] An alternative shape of a sensor 301b and heat sink 350b is shown in **FIGURE 3D**. The sensor 301b can include some or all of the features of the sensor 301a. For example, the sensor 301b includes an enclosure 302b formed by an emitter shell 304b and a detector shell 306b, pivotably connected about a pivot 303a. The emitter shell 304b can also include absorbing opaque material on one or more flaps 307b, and the detector shell 306a can also include absorbing opaque material at various areas, such as lower area 308b.

[0150] However, the shape of the sensor 301b is different in this embodiment. In particular, the heat sink 350b includes comb protrusions 351b. The comb protrusions 351b are exposed to the air in a similar manner to the fins 351a of the heat sink 350a, thereby facilitating efficient cooling of the sensor 301b.

[0151] **FIGURE 3E** illustrates a more detailed example of a detector shell 306b of the sensor 301b. The features described with respect to the detector shell 306b can also be used with the detector shell 306a of the sensor 301a.

[0152] As shown, the detector shell 306b includes detectors 316. The detectors 316 can have a predetermined spacing 340 from each other, or a spatial relationship among one another that results in a spatial configuration. This spatial configuration can purposefully create a variation of path lengths among detectors 316 and the emitter discussed above.

[0153] In the depicted embodiment, the detector shell 316 can hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays can also be useful to detect light piping (e.g., light that bypasses measurement site 102). In the detector shell 316, walls can be provided to separate the individual photodiode arrays to prevent or reduce mixing of light signals from distinct quadrants. In addition, the detector shell 316 can be covered by windows of transparent material, such as glass, plastic, or the like, to allow maximum or increased transmission of power light captured. In various embodiments, the transparent materials used can also be partially transparent or translucent or can otherwise pass some or all of the optical radiation passing through them. As noted, this window can include some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

[0154] As further illustrated by **FIGURE 3E**, the detectors 316 can have a spatial configuration of a grid. However, the detectors 316 can be arranged in other configurations that vary the path length. For example, the detectors 316 can be arranged in a linear array, a logarithmic array, a two-dimensional array, a zig-zag pattern, or the like. Furthermore, any number of the detectors 316 can be employed in certain embodiments.

[0155] **FIGURE 3F** illustrates another embodiment of a sensor 301f. The sensor 301f can include some or all of the features of the sensor 301a of **FIGURE 3A** described above. For example, the sensor 301f includes an enclosure 302f formed by an upper section or emitter shell 304f, which is pivotably connected with a lower section or detector shell 306f around a pivot point 303f. The emitter shell 304f can also include absorbing opaque material on various areas, such as on one or more flaps 307f, to reduce ambient light entering the sensor 301f. The detector shell 306f can also include absorbing opaque material at various areas, such as a

lower area 308f. The sensor 301f also includes a heat sink 350f, which includes fins 351f.

[0156] In addition to these features, the sensor 301f includes a flex circuit cover 360, which can be made of plastic or another suitable material. The flex circuit cover 360 can cover and thereby protect a flex circuit (not shown) that extends from the emitter shell 304f to the detector shell 306f. An example of such a flex circuit is illustrated in U.S. Publication No. 2006/0211924, incorporated above (see FIGURE 46 and associated description, which is hereby specifically incorporated by reference). The flex circuit cover 360 is shown in more detail below in FIGURE 17.

[0157] In addition, sensors 301a-f has extra length – extends to second joint on finger - Easier to place, harder to move due to cable, better for light piping

[0158] FIGURES 4A through 4C illustrate example arrangements of a protrusion 405, which is an embodiment of the protrusion 305 described above. In an embodiment, the protrusion 405 can include a measurement site contact area 470. The measurement site contact area 470 can include a surface that molds body tissue of a measurement site, such as a finger, into a flat or relatively flat surface.

[0159] The protrusion 405 can have dimensions that are suitable for a measurement site such as a patient's finger. As shown, the protrusion 405 can have a length 400, a width 410, and a height 430. The length 400 can be from about 9 to about 11 millimeters, e.g., about 10 millimeters. The width 410 can be from about 7 to about 9 millimeters, e.g., about 8 millimeters. The height 430 can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions 400, 410, and 430 can be selected such that the measurement site contact area 470 includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.

[0160] The measurement site contact area 470 can also include differently shaped surfaces that conform the measurement site into different shapes. For example, the measurement site contact area 470 can be generally curved and/or convex with respect to the measurement site. The measurement site contact area

470 can be other shapes that reduce or even minimize air between the protrusion 405 and or the measurement site. Additionally, the surface pattern of the measurement site contact area 470 can vary from smooth to bumpy, e.g., to provide varying levels of grip.

[0161] In **FIGURES 4A** and **4C**, openings or windows 420, 421, 422, and 423 can include a wide variety of shapes and sizes, including for example, generally square, circular, triangular, or combinations thereof. The windows 420, 421, 422, and 423 can be of non-uniform shapes and sizes. As shown, the windows 420, 421, 422, and 423 can be evenly spaced out in a grid like arrangement. Other arrangements or patterns of arranging the windows 420, 421, 422, and 423 are possible. For example, the windows 420, 421, 422, and 423 can be placed in a triangular, circular, or linear arrangement. In some embodiments, the windows 420, 421, 422, and 423 can be placed at different heights with respect to the finger bed 310 of **FIGURE 3**. The windows 420, 421, 422, and 423 can also mimic or approximately mimic a configuration of, or even house, a plurality of detectors.

[0162] **FIGURES 6A** through **6D** illustrate another embodiment of a protrusion 605 that can be used as the tissue shaper 105 described above or in place of the protrusions 305, 405 described above. The depicted protrusion 605 is a partially cylindrical lens having a partial cylinder 608 and an extension 610. The partial cylinder 608 can be a half cylinder in some embodiments; however, a smaller or greater portion than half of a cylinder can be used. Advantageously, in certain embodiments, the partially cylindrical protrusion 605 focuses light onto a smaller area, such that fewer detectors can be used to detect the light attenuated by a measurement site.

[0163] **FIGURE 6A** illustrates a perspective view of the partially cylindrical protrusion 605. **FIGURE 6B** illustrates a front elevation view of the partially cylindrical protrusion 605. **FIGURE 6C** illustrates a side view of the partially cylindrical protrusion 605. **FIGURE 6D** illustrates a top view of the partially cylindrical protrusion 605.

[0164] Advantageously, in certain embodiments, placing the partially cylindrical protrusion 605 over the photodiodes in any of the sensors described

above adds multiple benefits to any of the sensors described above. In one embodiment, the partially cylindrical protrusion 605 penetrates into the tissue and reduces the path length of the light traveling in the tissue, similar to the protrusions described above.

[0165] The partially cylindrical protrusion 605 can also collect light from a large surface and focus down the light to a smaller area. As a result, in certain embodiments, signal strength per area of the photodiode can be increased. The partially cylindrical protrusion 605 can therefore facilitate a lower cost sensor because, in certain embodiments, less photodiode area can be used to obtain the same signal strength. Less photodiode area can be realized by using smaller photodiodes or fewer photodiodes (see, e.g., FIGURE 14). If fewer or smaller photodiodes are used, the partially cylindrical protrusion 605 can also facilitate an improved SNR of the sensor because fewer or smaller photodiodes can have less dark current.

[0166] The dimensions of the partially cylindrical protrusion 605 can vary based on, for instance, a number of photodiodes used with the sensor. Referring to **FIGURE 6C**, the overall height of the partially cylindrical protrusion 605 (measurement “a”) in some implementations is about 1 to about 3 mm. A height in this range can allow the partially cylindrical protrusion 605 to penetrate into the pad of the finger or other tissue and reduce the distance that light travels through the tissue. Other heights, however, of the partially cylindrical protrusion 605 can also accomplish this objective. For example, the chosen height of the partially cylindrical protrusion 605 can be selected based on the size of the measurement site, whether the patient is an adult or child, and so on. In an embodiment, the height of the protrusion 605 is chosen to provide as much tissue thickness reduction as possible while reducing or preventing occlusion of blood vessels in the tissue.

[0167] Referring to **FIGURE 6D**, the width of the partially cylindrical protrusion 605 (measurement “b”) can be about 3 to about 5 mm. In one embodiment, the width is about 4 mm. In one embodiment, a width in this range provides good penetration of the partially cylindrical protrusion 605 into the tissue to reduce the path length of the light. Other widths, however, of the partially cylindrical

protrusion 605 can also accomplish this objective. For example, the width of the partially cylindrical protrusion 605 can vary based on the size of the measurement site, whether the patient is an adult or child, and so on. In addition, the length of the protrusion 605 could be about 10 mm, or about 8 mm to about 12 mm, or smaller than 8 mm or greater than 12 mm.

[0168] In certain embodiments, the focal length (f) for the partially cylindrical protrusion 605 can be expressed as: $f = \frac{R}{n-1}$, where R is the radius of curvature of the partial cylinder 608 and n is the index of refraction of the material used. In certain embodiments, the radius of curvature can be between about 1.5 mm and about 2 mm. In another embodiment, the partially cylindrical protrusion 605 can include a material, such as nBK7 glass, with an index of refraction of around 1.5 at 1300 nm, which can provide focal lengths of between about 3 mm and about 4 mm.

[0169] A partially cylindrical protrusion 605 having a material with a higher index of refraction such as nSF11 glass (e.g., $n=1.75$ at 1300 nm) can provide a shorter focal length and possibly a smaller photodiode chip, but can also cause higher reflections due to the index of refraction mismatch with air. Many types of glass or plastic can be used with index of refraction values ranging from, for example, about 1.4 to about 1.9. The index of refraction of the material of the protrusion 605 can be chosen to improve or optimize the light focusing properties of the protrusion 605. A plastic partially cylindrical protrusion 605 could provide the cheapest option in high volumes but can also have some undesired light absorption peaks at wavelengths higher than 1500 nm. Other focal lengths and materials having different indices of refraction can be used for the partially cylindrical protrusion 605.

[0170] Placing a photodiode at a given distance below the partially cylindrical protrusion 605 can facilitate capturing some or all of the light traveling perpendicular to the lens within the active area of the photodiode (see FIGURE 14). Different sizes of the partially cylindrical protrusion 605 can use different sizes of photodiodes. The extension 610 added onto the bottom of the partial cylinder 608 is

used in certain embodiments to increase the height of the partially cylindrical protrusion 605. In an embodiment, the added height is such that the photodiodes are at or are approximately at the focal length of the partially cylindrical protrusion 605. In an embodiment, the added height provides for greater thinning of the measurement site. In an embodiment, the added height assists in deflecting light piped through the sensor. This is because light piped around the sensor passes through the side walls of the added height without being directed toward the detectors. The extension 610 can also further facilitate the protrusion 605 increasing or maximizing the amount of light that is provided to the detectors. In some embodiments, the extension 610 can be omitted.

[0171] FIGURE 6E illustrates another view of the sensor 301f of FIGURE 3F, which includes an embodiment of a partially cylindrical protrusion 605b. Like the sensor 301A shown in FIGURES 3B and 3C, the sensor 301f includes a finger bed 310f. The finger bed 310f includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed 310f also includes the ridges or channels 314 described above with respect to FIGURES 3B and 3C.

[0172] The example of finger bed 310f shown also includes the protrusion 605b, which includes the features of the protrusion 605 described above. In addition, the protrusion 605b also includes chamfered edges 607 on each end to provide a more comfortable surface for a finger to slide across (see also FIGURE 14D). In another embodiment, the protrusion 605b could instead include a single chamfered edge 607 proximal to the ridges 314. In another embodiment, one or both of the chamfered edges 607 could be rounded.

[0173] The protrusion 605b also includes a measurement site contact area 670 that can contact body tissue of a measurement site. The protrusion 605b can be removed from or integrated with the finger bed 310f. Interchangeable, differently shaped protrusions 605b can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

[0174] FIGURES 7A and 7B illustrate block diagrams of sensors 701 that include example arrangements of conductive glass or conductive coated glass for shielding. Advantageously, in certain embodiments, the shielding can provide

increased SNR. The features of the sensors 701 can be implemented with any of the sensors 101, 201, 301 described above. Although not shown, the partially cylindrical protrusion 605 of FIGURE 6 can also be used with the sensors 701 in certain embodiments.

[0175] For example, referring specifically to **FIGURE 7A**, the sensor 701a includes an emitter housing 704a and a detector housing 706. The emitter housing 704a includes LEDs 104. The detector housing 706a includes a tissue bed 710a with an opening or window 703a, the conductive glass 730a, and one or more photodiodes for detectors 106 provided on a submount 707a.

[0176] During operation, a finger 102 can be placed on the tissue bed 710a and optical radiation can be emitted from the LEDs 104. Light can then be attenuated as it passes through or is reflected from the tissue of the finger 102. The attenuated light can then pass through the opening 703a in the tissue bed 710a. Based on the received light, the detectors 106 can provide a detector signal 107, for example, to the front end interface 108 (see FIGURE 1).

[0177] In the depicted embodiment, the conductive glass 730 is provided in the opening 703. The conductive glass 730 can thus not only permit light from the finger to pass to the detectors 106, but it can also supplement the shielding of the detectors 106 from noise. The conductive glass 730 can include a stack or set of layers. In **FIGURE 7A**, the conductive glass 730a is shown having a glass layer 731 proximate the finger 102 and a conductive layer 733 electrically coupled to the shielding 790a.

[0178] In an embodiment, the conductive glass 730a can be coated with a conductive, transparent or partially transparent material, such as a thin film of indium tin oxide (ITO). To supplement electrical shielding effects of a shielding enclosure 790a, the conductive glass 730a can be electrically coupled to the shielding enclosure 790a. The conductive glass 730a can be electrically coupled to the shielding 704a based on direct contact or via other connection devices, such as a wire or another component.

[0179] The shielding enclosure 790a can be provided to encompass the detectors 106 to reduce or prevent noise. For example, the shielding enclosure

790a can be constructed from a conductive material, such as copper, in the form of a metal cage. The shielding or enclosure a can include an opaque material to not only reduce electrical noise, but also ambient optical noise.

[0180] In some embodiments, the shielding enclosure 790a can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure 790a can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

[0181] Referring to **FIGURE 7B**, another block diagram of an example sensor 701b is shown. A tissue bed 710b of the sensor 701b includes a protrusion 705b, which is in the form of a convex bump. The protrusion 705b can include all of the features of the protrusions or tissue shaping materials described above. For example, the protrusion 705b includes a contact area 370 that comes in contact with the finger 102 and which can include one or more openings 703b. One or more components of conductive glass 730b can be provided in the openings 703. For example, in an embodiment, each of the openings 703 can include a separate window of the conductive glass 730b. In an embodiment, a single piece of the conductive glass 730b can be used for some or all of the openings 703b. The conductive glass 730b is smaller than the conductive glass 730a in this particular embodiment.

[0182] A shielding enclosure 790b is also provided, which can have all the features of the shielding enclosure 790a. The shielding enclosure 790b is smaller than the shielding enclosure 790a; however, a variety of sizes can be selected for the shielding enclosures 790.

[0183] In some embodiments, the shielding enclosure 790b can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure 790b can also be used to house various other components,

such as sigma delta components for various embodiments of front end interfaces 108.

[0184] **FIGURES 8A** through **8D** illustrate a perspective view, side views, and a bottom elevation view of the conductive glass described above with respect to the sensors 701a, 701b. As shown in the perspective view of **FIGURE 8A** and side view of **FIGURE 8B**, the conductive glass 730 includes the electrically conductive material 733 described above as a coating on the glass layer 731 described above to form a stack. In an embodiment where the electrically conductive material 733 includes indium tin oxide, surface resistivity of the electrically conductive material 733 can range approximately from 30 ohms per square inch to 500 ohms per square inch, or approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than 30 ohms or more than 500 ohms. Other transparent, electrically conductive materials can be used as the material 733.

[0185] Although the conductive material 733 is shown spread over the surface of the glass layer 731, the conductive material 733 can be patterned or provided on selected portions of the glass layer 731. Furthermore, the conductive material 733 can have uniform or varying thickness depending on a desired transmission of light, a desired shielding effect, and other considerations.

[0186] In **FIGURE 8C**, a side view of a conductive glass 830a is shown to illustrate an embodiment where the electrically conductive material 733 is provided as an internal layer between two glass layers 731, 835. Various combinations of integrating electrically conductive material 733 with glass are possible. For example, the electrically conductive material 733 can be a layer within a stack of layers. This stack of layers can include one or more layers of glass 731, 835, as well as one or more layers of conductive material 733. The stack can include other layers of materials to achieve desired characteristics.

[0187] In **FIGURE 8D**, a bottom perspective view is shown to illustrate an embodiment where a conductive glass 830b can include conductive material 837 that occupies or covers a portion of a glass layer 839. This embodiment can be useful, for example, to create individual, shielded windows for detectors 106, such

as those shown in FIGURE 3C. The conductive material 837 can be patterned to include an area 838 to allow light to pass to detectors 106 and one or more strips 841 to couple to the shielding 704 of FIGURE 7.

[0188] Other configurations and patterns for the conductive material can be used in certain embodiments, such as, for example, a conductive coating lining periphery edges, a conductive coating outlaid in a pattern including a grid or other pattern, a speckled conductive coating, coating outlaid in lines in either direction or diagonally, varied thicknesses from the center out or from the periphery in, or other suitable patterns or coatings that balance the shielding properties with transparency considerations.

[0189] FIGURE 9 depicts an example graph 900 that illustrates comparative results obtained by an example sensor having components similar to those disclosed above with respect to FIGURES 7 and 8. The graph 900 depicts the results of the percentage of transmission of varying wavelengths of light for different types of windows used in the sensors described above.

[0190] A line 915 on the graph 900 illustrates example light transmission of a window made from plain glass. As shown, the light transmission percentage of varying wavelengths of light is approximately 90% for a window made from plain glass. A line 920 on the graph 900 demonstrates an example light transmission percentage for an embodiment in which a window is made from glass having an ITO coating with a surface resistivity of 500 ohms per square inch. A line 925 on the graph 900 shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 200 ohms per square inch. A line 930 on the graph 900 shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 30 ohms per square inch.

[0191] The light transmission percentage for a window with currently available embedded wiring can have a light transmission percentage of approximately 70%. This lower percentage of light transmission can be due to the opacity of the wiring employed in a currently available window with wiring.

Accordingly, certain embodiments of glass coatings described herein can employ, for example, ITO coatings with different surface resistivity depending on the desired light transmission, wavelengths of light used for measurement, desired shielding effect, and other criteria.

[0192] FIGURES 10A through **10B** illustrate comparative noise floors of example implementations of the sensors described above. Noise can include optical noise from ambient light and electro-magnetic noise, for example, from surrounding electrical equipment. In **FIGURE 10A**, a graph 1000 depicts possible noise floors for different frequencies of noise for an embodiment in which one of the sensors described above included separate windows for four (4) detectors 106. One or more of the windows included an embedded grid of wiring as a noise shield. Symbols 1030 - 1033 illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance can vary for each of the openings and based on the frequency of the noise.

[0193] In **FIGURE 10B**, a graph 1050 depicts a noise floor for frequencies of noise 1070 for an embodiment in which the sensor included separate openings for four (4) detectors 106 and one or more windows that include an ITO coating. In this embodiment, a surface resistivity of the ITO used was about 500 ohms per square inch. Symbols 1080 - 1083 illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance for this embodiment can vary less for each of the openings and provide lower noise floors in comparison to the embodiment of **FIGURE 10A**.

[0194] FIGURE 11A illustrates an example structure for configuring the set of optical sources of the emitters described above. As shown, an emitter 104 can include a driver 1105, a thermistor 1120, a set of top-emitting LEDs 1102 for emitting red and/or infrared light, a set of side-emitting LEDs 1104 for emitting near infrared light, and a submount 1106.

[0195] The thermistor 1120 can be provided to compensate for temperature variations. For example, the thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 and 1104 due to heating. In addition, other thermistors (~~not shown~~) can be employed, for example, to measure a

temperature of a measurement site. The temperature can be displayed on a display device and used by a caregiver. Such a temperature can also be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose. In addition, using a thermistor or other type of temperature sensitive device may be useful for detecting extreme temperatures at the measurement site that are too hot or too cold. The presence of low perfusion may also be detected, for example, when the finger of a patient has become too cold. Moreover, shifts in temperature at the measurement site can alter the absorption spectrum of water and other tissue in the measurement site. A thermistor's temperature reading can be used to adjust for the variations in absorption spectrum changes in the measurement site.

[0196] The driver 1105 can provide pulses of current to the emitter 1104. In an embodiment, the driver 1105 drives the emitter 1104 in a progressive fashion, for example, in an alternating manner based on a control signal from, for example, a processor (e.g., the processor 110). For example, the driver 1105 can drive the emitter 1104 with a series of pulses to about 1 milliwatt (mW) for visible light to light at about 1300 nm and from about 40 mW to about 100 mW for light at about 1600 nm to about 1700 nm. However, a wide number of driving powers and driving methodologies can be used. The driver 1105 can be synchronized with other parts of the sensor and can minimize or reduce any jitter in the timing of pulses of optical radiation emitted from the emitter 1104. In some embodiments, the driver 1105 is capable of driving the emitter 1104 to emit an optical radiation in a pattern that varies by less than about 10 parts-per-million; however other amounts of variation can be used.

[0197] The submount 1106 provides a support structure in certain embodiments for aligning the top-emitting LEDs 1102 and the side-emitting LEDs 1104 so that their optical radiation is transmitted generally towards the measurement site. In some embodiments, the submount 1106 is also constructed of aluminum nitride (AlN) or beryllium oxide (BeO) for heat dissipation, although

other materials or combinations of materials suitable for the submount 1106 can be used.

[0198] **FIGURE 11B** illustrates a configuration of emitting optical radiation into a measurement site for measuring a blood constituent or analyte like glucose. In some embodiments, emitter 104 may be driven in a progressive fashion to minimize noise and increase SNR of sensor 101. For example, emitter 104 may be driven based on a progression of power/current delivered to LEDs 1102 and 1104.

[0199] In some embodiments, emitter 104 may be configured to emit pulses centered about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter 104 may emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, emitter 104 may be configured to transmit any of a variety of wavelengths of visible, or near-infrared optical radiation.

[0200] For purposes of illustration, **FIGURE 11B** shows a sequence of pulses of light at wavelengths of around 905 nm, around 1200 nm, around 1300 nm, and around 1330 nm from top emitting LEDs 1102. **FIGURE 11B** also shows that emitter 104 may then emit pulses centered at around 1630 nm, around 1660 nm, and around 1615 nm from side emitting LEDs 1104. Emitter 104 may be progressively driven at higher power/current. This progression may allow driver circuit 105 to stabilize in its operations, and thus, provide a more stable current/power to LEDs 1102 and 1104.

[0201] For example, as shown in **FIGURE 11B**, the sequence of optical radiation pulses are shown having a logarithmic-like progression in power/current. In some embodiments, the timing of these pulses is based on a cycle of about 400 slots running at 48 kHz (e.g. each time slot may be approximately 0.02 ms or 20 microseconds). An artisan will recognize that term “slots” includes its ordinary meaning, which includes a time period that may also be expressed in terms of a frequency. In the example shown, pulses from top emitting LEDs 1102 may have a pulse width of about 40 time slots (e.g., about 0.8 ms) and an off period of about 4

time slots in between. In addition, pulses from side emitting LEDs 1104 (e.g., or a laser diode) may have a pulse width of about 60 time slots (e.g., about 1.25 ms) and a similar off period of about 4 time slots. A pause of about 70 time slots (e.g. 1.5 ms) may also be provided in order to allow driver circuit 1105 to stabilize after operating at higher current/power.

[0202] As shown in **FIGURE 11B**, top emitting LEDs 1102 may be initially driven with a power to approximately 1 mW at a current of about 20-100 mA. Power in these LEDs may also be modulated by using a filter or covering of black dye to reduce power output of LEDs. In this example, top emitting LEDs 1102 may be driven at approximately 0.02 to 0.08 mW. The sequence of the wavelengths may be based on the current requirements of top emitting LEDs 502 for that particular wavelength. Of course, in other embodiments, different wavelengths and sequences of wavelengths may be output from emitter 104.

[0203] Subsequently, side emitting LEDs 1104 may be driven at higher powers, such as about 40-100 mW and higher currents of about 600-800 mA. This higher power may be employed in order to compensate for the higher opacity of tissue and water in measurement site 102 to these wavelengths. For example, as shown, pulses at about 1630 nm, about 1660 nm, and about 1615 nm may be output with progressively higher power, such as at about 40 mW, about 50 mW, and about 60 mW, respectively. In this embodiment, the order of wavelengths may be based on the optical characteristics of that wavelength in tissue as well as the current needed to drive side emitting LEDs 1104. For example, in this embodiment, the optical pulse at about 1615 nm is driven at the highest power due to its sensitivity in detecting analytes like glucose and the ability of light at this wavelength to penetrate tissue. Of course, different wavelengths and sequences of wavelengths may be output from emitter 104.

[0204] As noted, this progression may be useful in some embodiments because it allows the circuitry of driver circuit 1105 to stabilize its power delivery to LEDs 1102 and 1104. Driver circuit 1105 may be allowed to stabilize based on the duty cycle of the pulses or, for example, by configuring a variable waiting period to

allow for stabilization of driver circuit 1105. Of course, other variations in power/current and wavelength may also be employed in the present disclosure.

[0205] Modulation in the duty cycle of the individual pulses may also be useful because duty cycle can affect the signal noise ratio of the system 100. That is, as the duty cycle is increased so may the signal to noise ratio.

[0206] Furthermore, as noted above, driver circuit 1105 may monitor temperatures of the LEDs 1102 and 1104 using the thermistor 1120 and adjust the output of LEDs 1102 and 1104 accordingly. Such a temperature may be to help sensor 101 correct for wavelength drift due to changes in water absorption, which can be temperature dependent.

[0207] FIGURE 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. As shown, the emitter 104 can include components mounted on a substrate 1108 and on submount 1106. In particular, top-emitting LEDs 1102 for emitting red and/or infrared light may be mounted on substrate 1108. Side emitting LEDs 1104 may be mounted on submount 1106. As noted, side-emitting LEDs 1104 may be included in emitter 104 for emitting near infrared light.

[0208] As also shown, the sensor of **FIGURE 11C** may include a thermistor 1120. As noted, the thermistor 1120 can be provided to compensate for temperature variations. The thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 and 1104 due to heating. In addition, other thermistors (not shown) can be employed, for example, to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

[0209] In some embodiments, the emitter 104 may be implemented without the use of side emitting LEDs. For example, certain blood constituents, such as total hemoglobin, can be measured by embodiments of the disclosure without the use of side emitting LEDs. **FIGURE 11D** illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the

disclosure. In particular, an emitter 104 that is configured for a blood constituent, such as total hemoglobin, is shown. The emitter 104 can include components mounted on a substrate 1108. In particular, top-emitting LEDs 1102 for emitting red and/or infrared light may be mounted on substrate 1108.

[0210] As also shown, the emitter of **FIGURE 11D** may include a thermistor 1120. The thermistor 1120 can be provided to compensate for temperature variations. The thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 due to heating.

[0211] **FIGURE 12A** illustrates a detector submount 1200 having photodiode detectors that are arranged in a grid pattern on the detector submount 1200 to capture light at different quadrants from a measurement site. One detector submount 1200 can be placed under each window of the sensors described above, or multiple windows can be placed over a single detector submount 1200. The detector submount 1200 can also be used with the partially cylindrical protrusion 605 described above with respect to **FIGURE 6**.

[0212] The detectors include photodiode detectors 1-4 that are arranged in a grid pattern on the submount 1200 to capture light at different quadrants from the measurement site. As noted, other patterns of photodiodes, such as a linear row, or logarithmic row, can also be employed in certain embodiments.

[0213] As shown, the detectors 1-4 may have a predetermined spacing from each other, or spatial relationship among one another that result in a spatial configuration. This spatial configuration can be configured to purposefully create a variation of path lengths among detectors 106 and the point light source discussed above.

[0214] Detectors may hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays may also be useful to detect light piping (i.e., light that bypasses measurement site 102). As shown, walls may separate the individual photodiode arrays to prevent mixing of light signals from distinct quadrants. In addition, as noted, the detectors may be covered by windows of transparent material, such as glass, plastic, etc., to allow maximum transmission of power light captured. As

noted, this window may comprise some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

[0215] FIGURES 12B through 12D illustrate a simplified view of exemplary arrangements and spatial configurations of photodiodes for detectors 106. As shown, detectors 106 may comprise photodiode detectors 1-4 that are arranged in a grid pattern on detector submount 1200 to capture light at different quadrants from measurement site 102.

[0216] As noted, other patterns of photodiodes may also be employed in embodiments of the present disclosure, including, for example, stacked or other configurations recognizable to an artisan from the disclosure herein. For example, detectors 106 may be arranged in a linear array, a logarithmic array, a two-dimensional array, and the like. Furthermore, an artisan will recognize from the disclosure herein that any number of detectors 106 may be employed by embodiments of the present disclosure.

[0217] For example, as shown in **FIGURE 12B**, detectors 106 may comprise photodiode detectors 1-4 that are arranged in a substantially linear configuration on submount 1200. In this embodiment shown, photodiode detectors 1-4 are substantially equally spaced apart (e.g., where the distance D is substantially the same between detectors 1-4).

[0218] In **FIGURE 12C**, photodiode detectors 1-4 may be arranged in a substantially linear configuration on submount 1200, but may employ a substantially progressive, substantially logarithmic, or substantially semi-logarithmic spacing (e.g., where distances $D1 > D2 > D3$). This arrangement or pattern may be useful for use on a patient's finger and where the thickness of the finger gradually increases.

[0219] In **FIGURE 12D**, a different substantially grid pattern on submount 1200 of photodiode detectors 1-4 is shown. As noted, other patterns of detectors may also be employed in embodiments of the present invention.

[0220] FIGURES 12E through 12H illustrate several embodiments of photodiodes that may be used in detectors 106. As shown in these figures, a photodiode 1202 of detector 106 may comprise a plurality of active areas 1204,

These active areas 204 may be coupled together via a common cathode 1206 or anode 1208 in order to provide a larger effective detection area.

[0221] In particular, as shown in **FIGURE 12E**, photodiode 1202 may comprise two (2) active areas 1204a and 1204b. In **FIGURE 12F**, photodiode 1202 may comprise four (4) active areas 1204c-f. In **FIGURE 12G**, photodiode 1202 may comprise three (3) active areas 1204g-i. In **FIGURE 12H**, photodiode 1202 may comprise nine (9) active areas 1204j-r. The use of smaller active areas may be useful because smaller active areas can be easier to fabricate and can be fabricated with higher purity. However, one skilled in the art will recognize that various sizes of active areas may be employed in the photodiode 1202.

[0222] **FIGURE 13** illustrates an example multi-stream process 1300. The multi-stream process 1300 can be implemented by the data collection system 100 and/or by any of the sensors described above. As shown, a control signal from a signal processor 1310 controls a driver 1305. In response, an emitter 1304 generates a pulse sequence 1303 from its emitter (e.g., its LEDs) into a measurement site or sites 1302. As described above, in some embodiments, the pulse sequence 1303 is controlled to have a variation of about 10 parts per million or less. Of course, depending on the analyte desired, the tolerated variation in the pulse sequence 1303 can be greater (or smaller).

[0223] In response to the pulse sequence 1300, detectors 1 to n (n being an integer) in a detector 1306 capture optical radiation from the measurement site 1302 and provide respective streams of output signals. Each signal from one of detectors 1-n can be considered a stream having respective time slots corresponding to the optical pulses from emitter sets 1-n in the emitter 1304. Although n emitters and n detectors are shown, the number of emitters and detectors need not be the same in certain implementations.

[0224] A front end interface 1308 can accept these multiple streams from detectors 1-n and deliver one or more signals or composite signal(s) back to the signal processor 1310. A stream from the detectors 1-n can thus include measured light intensities corresponding to the light pulses emitted from the emitter 1304.

[0225] The signal processor 1310 can then perform various calculations to measure the amount of glucose and other analytes based on these multiple streams of signals. In order to help explain how the signal processor 1310 can measure analytes like glucose, a primer on the spectroscopy employed in these embodiments will now be provided.

[0226] Spectroscopy is premised upon the Beer-Lambert law. According to this law, the properties of a material, e.g., glucose present in a measurement site, can be deterministically calculated from the absorption of light traveling through the material. Specifically, there is a logarithmic relation between the transmission of light through a material and the concentration of a substance and also between the transmission and the length of the path traveled by the light. As noted, this relation is known as the Beer-Lambert law.

[0227] The Beer-Lambert law is usually written as:

[0228] Absorbance $A = m \cdot b \cdot c$, where:

[0229] m is the wavelength-dependent molar absorptivity coefficient (usually expressed in units of $M^{-1} \text{ cm}^{-1}$);

[0230] b is the mean path length; and

[0231] c is the analyte concentration (e.g., the desired parameter).

[0232] In spectroscopy, instruments attempt to obtain the analyte concentration (c) by relating absorbance (A) to transmittance (T). Transmittance is a proportional value defined as:

[0233] $T = I / I_0$, where:

[0234] I is the light intensity measured by the instrument from the measurement site; and

[0235] I_0 is the initial light intensity from the emitter.

[0236] Absorbance (A) can be equated to the transmittance (T) by the equation:

[0237] $A = -\log T$

[0238] Therefore, substituting equations from above:

[0239] $A = -\log (I / I_0)$

[0240] In view of this relationship, spectroscopy thus relies on a proportional-based calculation of $-\log(I / I_0)$ and solving for analyte concentration (c).

[0241] Typically, in order to simplify the calculations, spectroscopy will use detectors that are at the same location in order to keep the path length (b) a fixed, known constant. In addition, spectroscopy will employ various mechanisms to definitively know the transmission power (I_0), such as a photodiode located at the light source. This architecture can be viewed as a single channel or single stream sensor, because the detectors are at a single location.

[0242] However, this scheme can encounter several difficulties in measuring analytes, such as glucose. This can be due to the high overlap of absorption of light by water at the wavelengths relevant to glucose as well as other factors, such as high self-noise of the components.

[0243] Embodiments of the present disclosure can employ a different approach that in part allows for the measurement of analytes like glucose. Some embodiments can employ a bulk, non-pulsatile measurement in order to confirm or validate a pulsatile measurement. In addition, both the non-pulsatile and pulsatile measurements can employ, among other things, the multi-stream operation described above in order to attain sufficient SNR. In particular, a single light source having multiple emitters can be used to transmit light to multiple detectors having a spatial configuration.

[0244] A single light source having multiple emitters can allow for a range of wavelengths of light to be used. For example, visible, infrared, and near infrared wavelengths can be employed. Varying powers of light intensity for different wavelengths can also be employed.

[0245] Secondly, the use of multiple-detectors in a spatial configuration allow for a bulk measurement to confirm or validate that the sensor is positioned correctly. This is because the multiple locations of the spatial configuration can provide, for example, topology information that indicates where the sensor has been positioned. Currently available sensors do not provide such information. For example, if the bulk measurement is within a predetermined range of values, then this can indicate that the sensor is positioned correctly in order to perform pulsatile

measurements for analytes like glucose. If the bulk measurement is outside of a certain range or is an unexpected value, then this can indicate that the sensor should be adjusted, or that the pulsatile measurements can be processed differently to compensate, such as using a different calibration curve or adjusting a calibration curve. This feature and others allow the embodiments to achieve noise cancellation and noise reduction, which can be several times greater in magnitude than what is achievable by currently available technology.

[0246] In order to help illustrate aspects of the multi-stream measurement approach, the following example derivation is provided. Transmittance (T) can be expressed as:

$$\textbf{[0247]} \quad T = e^{-m*b*c}$$

[0248] In terms of light intensity, this equation can also be rewritten as:

$$\textbf{[0249]} \quad I / I_0 = e^{-m*b*c}$$

[0250] Or, at a detector, the measured light (I) can be expressed as:

$$\textbf{[0251]} \quad I = I_0 * e^{-m*b*c}$$

[0252] As noted, in the present disclosure, multiple detectors (1 to n) can be employed, which results in $I_1 \dots I_n$ streams of measurements. Assuming each of these detectors have their own path lengths, $b_1 \dots b_n$, from the light source, the measured light intensities can be expressed as:

$$\textbf{[0253]} \quad I_n = I_0 * e^{-m*b_n*c}$$

[0254] The measured light intensities at any two different detectors can be referenced to each other. For example:

$$\textbf{[0255]} \quad I_1/I_n = (I_0 * e^{-mb_1c}) / (I_0 * e^{-mb_nc})$$

[0256] As can be seen, the terms, I_0 , cancel out and, based on exponent algebra, the equation can be rewritten as:

$$\textbf{[0257]} \quad I_1/I_n = e^{-m(b_1-b_n)c}$$

[0258] From this equation, the analyte concentration (c) can now be derived from bulk signals $I_1 \dots I_n$ and knowing the respective mean path lengths b_1 and b_n . This scheme also allows for the cancelling out of I_0 , and thus, noise generated by the emitter 1304 can be cancelled out or reduced. In addition, since

the scheme employs a mean path length difference, any changes in mean path length and topological variations from patient to patient are easily accounted. Furthermore, this bulk-measurement scheme can be extended across multiple wavelengths. This flexibility and other features allow embodiments of the present disclosure to measure blood analytes like glucose.

[0259] For example, as noted, the non-pulsatile, bulk measurements can be combined with pulsatile measurements to more accurately measure analytes like glucose. In particular, the non-pulsatile, bulk measurement can be used to confirm or validate the amount of glucose, protein, etc. in the pulsatile measurements taken at the tissue at the measurement site(s) 1302. The pulsatile measurements can be used to measure the amount of glucose, hemoglobin, or the like that is present in the blood. Accordingly, these different measurements can be combined to thus determine analytes like blood glucose.

[0260] **FIGURE 14A** illustrates an embodiment of a detector submount 1400a positioned beneath the partially cylindrical protrusion 605 of FIGURE 6 (or alternatively, the protrusion 605b). The detector submount 1400a includes two rows 1408a of detectors 1410a. The partially cylindrical protrusion 605 can facilitate reducing the number and/or size of detectors used in a sensor because the protrusion 605 can act as a lens that focuses light onto a smaller area.

[0261] To illustrate, in some sensors that do not include the partially cylindrical protrusion 605, sixteen detectors can be used, including four rows of four detectors each. Multiple rows of detectors can be used to measure certain analytes, such as glucose or total hemoglobin, among others. Multiple rows of detectors can also be used to detect light piping (e.g., light that bypasses the measurement site). However, using more detectors in a sensor can add cost, complexity, and noise to the sensor.

[0262] Applying the partially cylindrical protrusion 605 to such a sensor, however, could reduce the number of detectors or rows of detectors used while still receiving the substantially same amount of light, due to the focusing properties of the protrusion 605 (see FIGURE 14B). This is the example situation illustrated in **FIGURE 14**—two rows 1408a of detectors 1410a are used instead of four.

Advantageously, in certain embodiments, the resulting sensor can be more cost effective, have less complexity, and have an improved SNR, due to fewer and/or smaller photodiodes.

[0263] In other embodiments, using the partially cylindrical protrusion 605 can allow the number of detector rows to be reduced to one or three rows of four detectors. The number of detectors in each row can also be reduced. Alternatively, the number of rows might not be reduced but the size of the detectors can be reduced. Many other configurations of detector rows and sizes can also be provided.

[0264] **FIGURE 14B** depicts a front elevation view of the partially cylindrical protrusion 605 (or alternatively, the protrusion 605b) that illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors. The protrusion 605 is placed above a detector submount 1400b having one or more detectors 1410b disposed thereon. The submount 1400b can include any number of rows of detectors 1410, although one row is shown.

[0265] Light, represented by rays 1420, is emitted from the emitters onto the protrusion 605. These light rays 1420 can be attenuated by body tissue (not shown). When the light rays 1420 enter the protrusion 605, the protrusion 605 acts as a lens to refract the rays into rays 1422. This refraction is caused in certain embodiments by the partially cylindrical shape of the protrusion 605. The refraction causes the rays 1422 to be focused or substantially focused on the one or more detectors 1410b. Since the light is focused on a smaller area, a sensor including the protrusion 605 can include fewer detectors to capture the same amount of light compared with other sensors.

[0266] **FIGURE 14C** illustrates another embodiment of a detector submount 1400c, which can be disposed under the protrusion 605b (or alternatively, the protrusion 605). The detector submount 1400c includes a single row 1408c of detectors 1410c. The detectors are electrically connected to conductors 1412c, which can be gold, silver, copper, or any other suitable conductive material.

[0267] The detector submount 1400c is shown positioned under the protrusion 605b in a detector subassembly 1450 illustrated in **FIGURE 14D**. A top-

down view of the detector subassembly 1450 is also shown in **FIGURE 14E**. In the detector subassembly 1450, a cylindrical housing 1430 is disposed on the submount 1400c. The cylindrical housing 1430 includes a transparent cover 1432, upon which the protrusion 605b is disposed. Thus, as shown in **FIGURE 14D**, a gap 1434 exists between the detectors 1410c and the protrusion 605b. The height of this gap 1434 can be chosen to increase or maximize the amount of light that impinges on the detectors 1410c.

[0268] The cylindrical housing 1430 can be made of metal, plastic, or another suitable material. The transparent cover 1432 can be fabricated from glass or plastic, among other materials. The cylindrical housing 1430 can be attached to the submount 1400c at the same time or substantially the same time as the detectors 1410c to reduce manufacturing costs. A shape other than a cylinder can be selected for the housing 1430 in various embodiments.

[0269] In certain embodiments, the cylindrical housing 1430 (and transparent cover 1432) forms an airtight or substantially airtight or hermetic seal with the submount 1400c. As a result, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c from fluids and vapors that can cause corrosion. Advantageously, in certain embodiments, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c more effectively than currently-available resin epoxies, which are sometimes applied to solder joints between conductors and detectors.

[0270] In embodiments where the cylindrical housing 1430 is at least partially made of metal, the cylindrical housing 1430 can provide noise shielding for the detectors 1410c. For example, the cylindrical housing 1430 can be soldered to a ground connection or ground plane on the submount 1400c, which allows the cylindrical housing 1430 to reduce noise. In another embodiment, the transparent cover 1432 can include a conductive material or conductive layer, such as conductive glass or plastic. The transparent cover 1432 can include any of the features of the noise shields 790 described above.

[0271] The protrusion 605b includes the chamfered edges 607 described above with respect to **FIGURE 6E**. These chamfered edges 607 can allow a patient

to more comfortably slide a finger over the protrusion 605b when inserting the finger into the sensor 301f.

[0272] **FIGURE 14F** illustrates a portion of the detector shell 306f, which includes the detectors 1410c on the substrate 1400c. The substrate 1400c is enclosed by a shielding enclosure 1490, which can include the features of the shielding enclosures 790a, 790b described above (see also FIGURE 17). The shielding enclosure 1490 can be made of metal. The shielding enclosure 1490 includes a window 1492a above the detectors 1410c, which allows light to be transmitted onto the detectors 1410c.

[0273] A noise shield 1403 is disposed above the shielding enclosure 1490. The noise shield 1403, in the depicted embodiment, includes a window 1492a corresponding to the window 1492a. Each of the windows 1492a, 1492b can include glass, plastic, or can be an opening without glass or plastic. In some embodiments, the windows 1492a, 1492b may be selected to have different sizes or shapes from each other.

[0274] The noise shield 1403 can include any of the features of the conductive glass described above. In the depicted embodiment, the noise shield 1403 extends about three-quarters of the length of the detector shell 306f. In other embodiments, the noise shield 1403 could be smaller or larger. The noise shield 1403 could, for instance, merely cover the detectors 1410c, the submount 1400c, or a portion thereof. The noise shield 1403 also includes a stop 1413 for positioning a measurement site within the sensor 301f. Advantageously, in certain embodiments, the noise shield 1403 can reduce noise caused by light piping.

[0275] A thermistor 1470 is also shown. The thermistor 1470 is attached to the submount 1400c and protrudes above the noise shield 1403. As described above, the thermistor 1470 can be employed to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

[0276] In the depicted embodiment, the detectors 1410c are not enclosed in the cylindrical housing 1430. In an alternative embodiment, the cylindrical housing 1430 encloses the detectors 1410c and is disposed under the noise shield 1403. In another embodiment, the cylindrical housing 1430 encloses the detectors 1410c and the noise shield 1403 is not used. If both the cylindrical housing 1403 and the noise shield 1403 are used, either or both can have noise shielding features.

[0277] **FIGURE 14G** illustrates the detector shell 306f of **FIGURE 14F**, with the finger bed 310f disposed thereon. **FIGURE 14H** illustrates the detector shell 306f of **FIGURE 14G**, with the protrusion 605b disposed in the finger bed 310f.

[0278] **FIGURE 14I** illustrates a cutaway view of the sensor 301f. Not all features of the sensor 301f are shown, such as the protrusion 605b. Features shown include the emitter and detector shells 304f, 306f, the flaps 307f, the heat sink 350f and fins 351f, the finger bed 310f, and the noise shield 1403.

[0279] In addition to these features, emitters 1404 are depicted in the emitter shell 304f. The emitters 1404 are disposed on a submount 1401, which is connected to a circuit board 1419. The emitters 1404 are also enclosed within a cylindrical housing 1480. The cylindrical housing 1480 can include all of the features of the cylindrical housing 1430 described above. For example, the cylindrical housing 1480 can be made of metal, can be connected to a ground plane of the submount 1401 to provide noise shielding, and can include a transparent cover 1482.

[0280] The cylindrical housing 1480 can also protect the emitters 1404 from fluids and vapors that can cause corrosion. Moreover, the cylindrical housing 1480 can provide a gap between the emitters 1404 and the measurement site (not shown), which can allow light from the emitters 1404 to even out or average out before reaching the measurement site.

[0281] The heat sink 350f, in addition to including the fins 351f, includes a protuberance 352f that extends down from the fins 351f and contacts the submount 1401. The protuberance 352f can be connected to the submount 1401, for

example, with thermal paste or the like. The protuberance 352f can sink heat from the emitters 1404 and dissipate the heat via the fins 351f.

[0282] FIGURES 15A and 15B illustrate embodiments of sensor portions 1500A, 1500B that include alternative heat sink features to those described above. These features can be incorporated into any of the sensors described above. For example, any of the sensors above can be modified to use the heat sink features described below instead of or in addition to the heat sink features of the sensors described above.

[0283] The sensor portions 1500A, 1500B shown include LED emitters 1504; however, for ease of illustration, the detectors have been omitted. The sensor portions 1500A, 1500B shown can be included, for example, in any of the emitter shells described above.

[0284] The LEDs 1504 of the sensor portions 1500A, 1500B are connected to a substrate or submount 1502. The submount 1502 can be used in place of any of the submounts described above. The submount 1502 can be a non-electrically conducting material made of any of a variety of materials, such as ceramic, glass, or the like. A cable 1512 is attached to the submount 1502 and includes electrical wiring 1514, such as twisted wires and the like, for communicating with the LEDs 1504. The cable 1512 can correspond to the cables 212 described above.

[0285] Although not shown, the cable 1512 can also include electrical connections to a detector. Only a portion of the cable 1512 is shown for clarity. The depicted embodiment of the cable 1512 includes an outer jacket 1510 and a conductive shield 1506 disposed within the outer jacket 1510. The conductive shield 1506 can be a ground shield or the like that is made of a metal such as braided copper or aluminum. The conductive shield 1506 or a portion of the conductive shield 1506 can be electrically connected to the submount 1502 and can reduce noise in the signal generated by the sensor 1500A, 1500B by reducing RF coupling with the wires 1514. In alternative embodiments, the cable 1512 does not have a conductive shield. For example, the cable 1512 could be a twisted pair cable or the like, with one wire of the twisted pair used as a heat sink.

[0286] Referring specifically to **FIGURE 15A**, in certain embodiments, the conductive shield 1506 can act as a heat sink for the LEDs 1504 by absorbing thermal energy from the LEDs 1504 and/or the submount 1502. An optional heat insulator 1520 in communication with the submount 1502 can also assist with directing heat toward the conductive shield 1506. The heat insulator 1520 can be made of plastic or another suitable material. Advantageously, using the conductive shield 1506 in the cable 1512 as a heat sink can, in certain embodiments, reduce cost for the sensor.

[0287] Referring to **FIGURE 15B**, the conductive shield 1506 can be attached to both the submount 1502 and to a heat sink layer 1530 sandwiched between the submount 1502 and the optional insulator 1520. Together, the heat sink layer 1530 and the conductive shield 1506 in the cable 1512 can absorb at least part of the thermal energy from the LEDs and/or the submount 1502.

[0288] **FIGURES 15C** and **15D** illustrate implementations of a sensor portion 1500C that includes the heat sink features of the sensor portion 1500A described above with respect to **FIGURE 15A**. The sensor portion 1500C includes the features of the sensor portion 1500A, except that the optional insulator 1520 is not shown. **FIGURE 15D** is a side cutaway view of the sensor portion 1500C that shows the emitters 1504.

[0289] The cable 1512 includes the outer jacket 1510 and the conductive shield 1506. The conductive shield 1506 is soldered to the submount 1502, and the solder joint 1561 is shown. In some embodiments, a larger solder joint 1561 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, a cylindrical housing 1580, corresponding to the cylindrical housing 1480 of **FIGURE 14I**, is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

[0290] **FIGURES 15E** and **15F** illustrate implementations of a sensor portion 1500E that includes the heat sink features of the sensor portion 1500B described above with respect to **FIGURE 15B**. The sensor portion 1500E includes the heat sink layer 1530. The heat sink layer 1530 can be a metal plate, such as a

copper plate or the like. The optional insulator 1520 is not shown. **FIGURE 15F** is a side cutaway view of the sensor portion 1500E that shows the emitters 1504.

[0291] In the depicted embodiment, the conductive shield 1506 of the cable 1512 is soldered to the heat sink layer 1530 instead of the submount 1502. The solder joint 1565 is shown. In some embodiments, a larger solder joint 1565 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, the cylindrical housing 1580 is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

[0292] **FIGURES 15G** and **15H** illustrate embodiments of connector features that can be used with any of the sensors described above with respect to **FIGURES 1** through **15F**. Referring to **FIGURE 15G**, the circuit board 1519 includes a female connector 1575 that mates with a male connector 1577 connected to a daughter board 1587. The daughter board 1587 includes connections to the electrical wiring 1514 of the cable 1512. The connected boards 1519, 1587 are shown in **FIGURE 15H**. Also shown is a hole 1573 that can receive the cylindrical housing 1580 described above.

[0293] Advantageously, in certain embodiments, using a daughter board 1587 to connect to the circuit board 1519 can enable connections to be made more easily to the circuit board 1519. In addition, using separate boards can be easier to manufacture than a single circuit board 1519 with all connections soldered to the circuit board 1519.

[0294] **FIGURE 15I** illustrates an exemplary architecture for front-end interface 108 as a transimpedance-based front-end. As noted, front-end interfaces 108 provide an interface that adapts the output of detectors 106 into a form that can be handled by signal processor 110. As shown in this figure, sensor 101 and front-end interfaces 108 may be integrated together as a single component, such as an integrated circuit. Of course, one skilled in the art will recognize that sensor 101 and front end interfaces 108 may comprise multiple components or circuits that are coupled together.

[0295] Front-end interfaces 108 may be implemented using transimpedance amplifiers that are coupled to analog to digital converters in a sigma delta converter. In some embodiments, a programmable gain amplifier (PGA) can be used in combination with the transimpedance-based front-ends. For example, the output of a transimpedance-based front-end may be output to a sigma-delta ADC that comprises a PGA. A PGA may be useful in order to provide another level of amplification and control of the stream of signals from detectors 106. The PGA may be an integrated circuit or built from a set of micro-relays. Alternatively, the PGA and ADC components in converter 900 may be integrated with the transimpedance-based front-end in sensor 101.

[0296] Due to the low-noise requirements for measuring blood analytes like glucose and the challenge of using multiple photodiodes in detector 106, the applicants developed a noise model to assist in configuring front-end 108. Conventionally, those skilled in the art have focused on optimizing the impedance of the transimpedance amplifiers to minimize noise.

[0297] However, the following noise model was discovered by the applicants:

$$Noise = \sqrt{aR + bR^2}, \text{ where:}$$

[0298] aR is characteristic of the impedance of the transimpedance amplifier; and

[0299] bR^2 is characteristic of the impedance of the photodiodes in detector and the number of photodiodes in detector 106.

[0300] The foregoing noise model was found to be helpful at least in part due to the high SNR required to measure analytes like glucose. However, the foregoing noise model was not previously recognized by artisans at least in part because, in conventional devices, the major contributor to noise was generally believed to originate from the emitter or the LEDs. Therefore, artisans have generally continued to focus on reducing noise at the emitter.

[0301] However, for analytes like glucose, the discovered noise model revealed that one of the major contributors to noise was generated by the photodiodes. In addition, the amount of noise varied based on the number of

photodiodes coupled to a transimpedance amplifier. Accordingly, combinations of various photodiodes from different manufacturers, different impedance values with the transimpedance amplifiers, and different numbers of photodiodes were tested as possible embodiments.

[0302] In some embodiments, different combinations of transimpedance to photodiodes may be used. For example, detectors 1-4 (as shown, e.g., in **FIGURE 12A**) may each comprise four photodiodes. In some embodiments, each detector of four photodiodes may be coupled to one or more transimpedance amplifiers. The configuration of these amplifiers may be set according to the model shown in **FIGURE 15J**.

[0303] Alternatively, each of the photodiodes may be coupled to its own respective transimpedance amplifier. For example, transimpedance amplifiers may be implemented as integrated circuits on the same circuit board as detectors 1-4. In this embodiment, the transimpedance amplifiers may be grouped into an averaging (or summing) circuit, which are known to those skilled in the art, in order to provide an output stream from the detector. The use of a summing amplifier to combine outputs from several transimpedance amplifiers into a single, analog signal may be helpful in improving the SNR relative to what is obtainable from a single transimpedance amplifier. The configuration of the transimpedance amplifiers in this setting may also be set according to the model shown in **FIGURE 15J**.

[0304] As yet another alternative, as noted above with respect to **FIGURES 12E** through **12H**, the photodiodes in detectors 106 may comprise multiple active areas that are grouped together. In some embodiments, each of these active areas may be provided its own respective transimpedance. This form of pairing may allow a transimpedance amplifier to be better matched to the characteristics of its corresponding photodiode or active area of a photodiode.

[0305] As noted, **FIGURE 15J** illustrates an exemplary noise model that may be useful in configuring transimpedance amplifiers. As shown, for a given number of photodiodes and a desired SNR, an optimal impedance value for a transimpedance amplifier could be determined.

[0306] For example, an exemplary “4 PD per stream” sensor 1502 is shown where detector 106 comprises four photodiodes 1502. The photodiodes 1502 are coupled to a single transimpedance amplifier 1504 to produce an output stream 1506. In this example, the transimpedance amplifier comprises 10 M Ω resistors 1508 and 1510. Thus, output stream 1506 is produced from the four photodiodes (PD) 1502. As shown in the graph of **FIGURE 15J**, the model indicates that resistance values of about 10 M Ω may provide an acceptable SNR for analytes like glucose.

[0307] However, as a comparison, an exemplary “1 PD per stream” sensor 1512 is also shown in **FIGURE 15J**. In particular, sensor 1512 may comprise a plurality of detectors 106 that each comprises a single photodiode 1514. In addition, as shown for this example configuration, each of photodiodes 1514 may be coupled to respective transimpedance amplifiers 1516, e.g., 1 PD per stream. Transimpedance amplifiers are shown having 40 M Ω resistors 1518. As also shown in the graph of **FIGURE 15J**, the model illustrates that resistance values of 40 M Ω for resistors 1518 may serve as an alternative to the 4 photodiode per stream architecture of sensor 1502 described above and yet still provide an equivalent SNR.

[0308] Moreover, the discovered noise model also indicates that utilizing a 1 photodiode per stream architecture like that in sensor 1512 may provide enhanced performance because each of transimpedance amplifiers 1516 can be tuned or optimized to its respective photodiodes 1518. In some embodiments, an averaging component 1520 may also be used to help cancel or reduce noise across photodiodes 1518.

[0309] For purposes of illustration, **FIGURE 15K** shows different architectures (e.g., four PD per stream and one PD per stream) for various embodiments of a sensor and how components of the sensor may be laid out on a circuit board or substrate. For example, sensor 1522 may comprise a “4 PD per stream” architecture on a submount 700 in which each detector 106 comprises four (4) photodiodes 1524. As shown for sensor 1522, the output of each set of four

photodiodes 1524 is then aggregated into a single transimpedance amplifier 1526 to produce a signal.

[0310] As another example, a sensor 1528 may comprise a “1 PD per stream” architecture on submount 700 in which each detector 106 comprises four (4) photodiodes 1530. In sensor 1528, each individual photodiode 1530 is coupled to a respective transimpedance amplifier 1532. The output of the amplifiers 1532 may then be aggregated into averaging circuit 1520 to produce a signal.

[0311] As noted previously, one skilled in the art will recognize that the photodiodes and detectors may be arranged in different fashions to optimize the detected light. For example, sensor 1534 illustrates an exemplary “4 PD per stream” sensor in which the detectors 106 comprise photodiodes 1536 arranged in a linear fashion. Likewise, sensor 1538 illustrates an exemplary “1 PD per stream” sensor in which the detectors comprise photodiodes 1540 arranged in a linear fashion.

[0312] Alternatively, sensor 1542 illustrates an exemplary “4 PD per stream” sensor in which the detectors 106 comprise photodiodes 1544 arranged in a two-dimensional pattern, such as a zig-zag pattern. Sensor 1546 illustrates an exemplary “1 PD per stream” sensor in which the detectors comprise photodiodes 1548 also arranged in a zig-zag pattern.

[0313] **FIGURE 15L** illustrates an exemplary architecture for a switched-capacitor-based front-end. As shown, front-end interfaces 108 may be implemented using switched capacitor circuits and any number of front-end interfaces 108 may be implemented. The output of these switched capacitor circuits may then be provided to a digital interface 1000 and signal processor 110. Switched capacitor circuits may be useful in system 100 for their resistor free design and analog averaging properties. In particular, the switched capacitor circuitry provides for analog averaging of the signal that allows for a lower smaller sampling rate (e.g., 2 KHz sampling for analog versus 48 KHz sampling for digital designs) than similar digital designs. In some embodiments, the switched capacitor architecture in front end interfaces 108 may provide a similar or equivalent SNR to other front end designs, such as a sigma delta architecture. In addition, a switched capacitor design in front

end interfaces 108 may require less computational power by signal processor 110 to perform the same amount of decimation to obtain the same SNR.

[0314] FIGURES 16A and 16B illustrate embodiments of disposable optical sensors 1600. In an embodiment, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be incorporated into the disposable sensors 1600 shown. For instance, the sensors 1600 can be used as the sensors 101 in the system 100 described above with respect to FIGURE 1. Moreover, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be implemented in other disposable sensor designs that are not depicted herein.

[0315] The sensors 1600 include an adult/pediatric sensor 1610 for finger placement and a disposable infant/neonate sensor 1602 configured for toe, foot or hand placement. Each sensor 1600 has a tape end 1610 and an opposite connector end 1620 electrically and mechanically interconnected via a flexible coupling 1630. The tape end 1610 attaches an emitter and detector to a tissue site. Although not shown, the tape end 1610 can also include any of the protrusion, shielding, and/or heat sink features described above. The emitter illuminates the tissue site and the detector generates a sensor signal responsive to the light after tissue absorption, such as absorption by pulsatile arterial blood flow within the tissue site.

[0316] The sensor signal is communicated via the flexible coupling 1630 to the connector end 1620. The connector end 1620 can mate with a cable (not shown) that communicates the sensor signal to a monitor (not shown), such as any of the cables or monitors shown above with respect to FIGURES 2A through 2D. Alternatively, the connector end 1620 can mate directly with the monitor.

[0317] FIGURE 17 illustrates an exploded view of certain of the components of the sensor 301f described above. A heat sink 1751 and a cable 1781 attach to an emitter shell 1704. The emitter shell attaches to a flap housing 1707. The flap housing 1707 includes a receptacle 1709 to receive a cylindrical housing 1480/1580 (not shown) attached to an emitter submount 1702, which is attached to a circuit board 1719.

[0318] A spring 1787 attaches to a detector shell 1706 via pins 1783, 1785, which hold the emitter and detector shells 1704, 1706 together. A support structure 1791 attaches to the detector shell 1706, which provides support for a shielding enclosure 1790. A noise shield 1713 attaches to the shielding enclosure 1790. A detector submount 1700 is disposed inside the shielding enclosure 1790. A finger bed 1710 provides a surface for placement of the patient's finger. Finger bed 1710 may comprise a gripping surface or gripping features, which may assist in placing and stabilizing a patient's finger in the sensor. A partially cylindrical protrusion 1705 may also be disposed in the finger bed 1710. As shown, finger bed 1710 attaches to the noise shield 1703. The noise shield 1703 may be configured to reduce noise, such as from ambient light and electromagnetic noise. For example, the noise shield 1703 may be constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping.

[0319] Noise shield 1703 may also comprise a thermistor 1712. The thermistor 1712 may be helpful in measuring the temperature of a patient's finger. For example, the thermistor 1712 may be useful in detecting when the patient's finger is reaching an unsafe temperature that is too hot or too cold. In addition, the temperature of the patient's finger may be useful in indicating to the sensor the presence of low perfusion as the temperature drops. In addition, the thermistor 1712 may be useful in detecting a shift in the characteristics of the water spectrum in the patient's finger, which can be temperature dependent.

[0320] Moreover, a flex circuit cover 1706 attaches to the pins 1783, 1785. Although not shown, a flex circuit can also be provided that connects the circuit board 1719 with the submount 1700 (or a circuit board to which the submount 1700 is connected). A flex circuit protector 1760 may be provided to provide a barrier or shield to the flex circuit (not shown). In particular, the flex circuit protector 1760 may also prevent any electrostatic discharge to or from the flex circuit. The flex circuit protector 1760 may be constructed from well known materials, such as a plastic or rubber materials.

[0321] **FIGURE 18** shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This

sensor 101 was tested using a pure water ex-vivo sample. In particular, ten samples were prepared that ranged from 0-55 mg/dL. Two samples were used as a training set and eight samples were then used as a test population. As shown, embodiments of the sensor 101 were able to obtain at least a standard deviation of 13 mg/dL in the training set and 11 mg/dL in the test population.

[0322] **FIGURE 19** shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a turbid ex-vivo sample. In particular, 25 samples of water/glucose/Lyposin were prepared that ranged from 0-55 mg/dL. Five samples were used as a training set and 20 samples were then used as a test population. As shown, embodiments of sensor 101 were able to obtain at least a standard deviation of 37 mg/dL in the training set and 32 mg/dL in the test population.

[0323] **FIGURES 20** through **22** shows other results that can be obtained by an embodiment of system 100. In **FIGURE 20**, 150 blood samples from two diabetic adult volunteers were collected over a 10-day period. Invasive measurements were taken with a YSI glucometer to serve as a reference measurement. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs and four independent detector streams. As shown, the system 100 obtained a correlation of about 85% and Arms of about 31 mg/dL.

[0324] In **FIGURE 21**, 34 blood samples were taken from a diabetic adult volunteer collected over a 2-day period. Invasive measurements were also taken with a glucometer for comparison. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector streams from detectors 106. As shown, the system 100 was able to attain a correlation of about 90% and Arms of about 22 mg/dL.

[0325] The results shown in **FIGURE 22** relate to total hemoglobin testing with an exemplary sensor 101 of the present disclosure. In particular, 47 blood samples were collected from nine adult volunteers. Invasive measurements were then taken with a CO-oximeter for comparison. Noninvasive measurements were taken with an embodiment of system 100 that comprised four LEDs in emitter 104

and four independent detector channels from detectors 106. Measurements were averaged over 1 minute. As shown, the testing resulted in a correlation of about 93% and Arms of about 0.8 mg/dL.

[0326] Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment.

[0327] While certain embodiments of the inventions disclosed herein have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of the inventions disclosed herein. Indeed, the novel methods and systems described herein can be embodied in a variety of other forms; furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein can be made without departing from the spirit of the inventions disclosed herein. The claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of certain of the inventions disclosed herein.

WHAT IS CLAIMED IS:

1. A noninvasive sensor capable of producing a signal responsive to light attenuated by tissue at a measurement site on a patient, the sensor comprising:
 - an optical source configured to emit optical radiation onto said tissue at said measurement site;
 - at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation;
 - a housing positioning said optical source and said at least one photodetector with respect to said measurement site;
 - a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site.

ABSTRACT OF THE DISCLOSURE

The present disclosure relates to noninvasive methods, devices, and systems for measuring various blood constituents or analytes, such as glucose. In an embodiment, a light source comprises LEDs and super-luminescent LEDs. The light source emits light at least wavelengths of about 1610 nm, about 1640 nm, and about 1665 nm. In an embodiment, the detector comprises a plurality of photodetectors arranged in a special geometry comprising one of a substantially linear substantially equal spaced geometry, a substantially linear substantially non-equal spaced geometry, and a substantially grid geometry.



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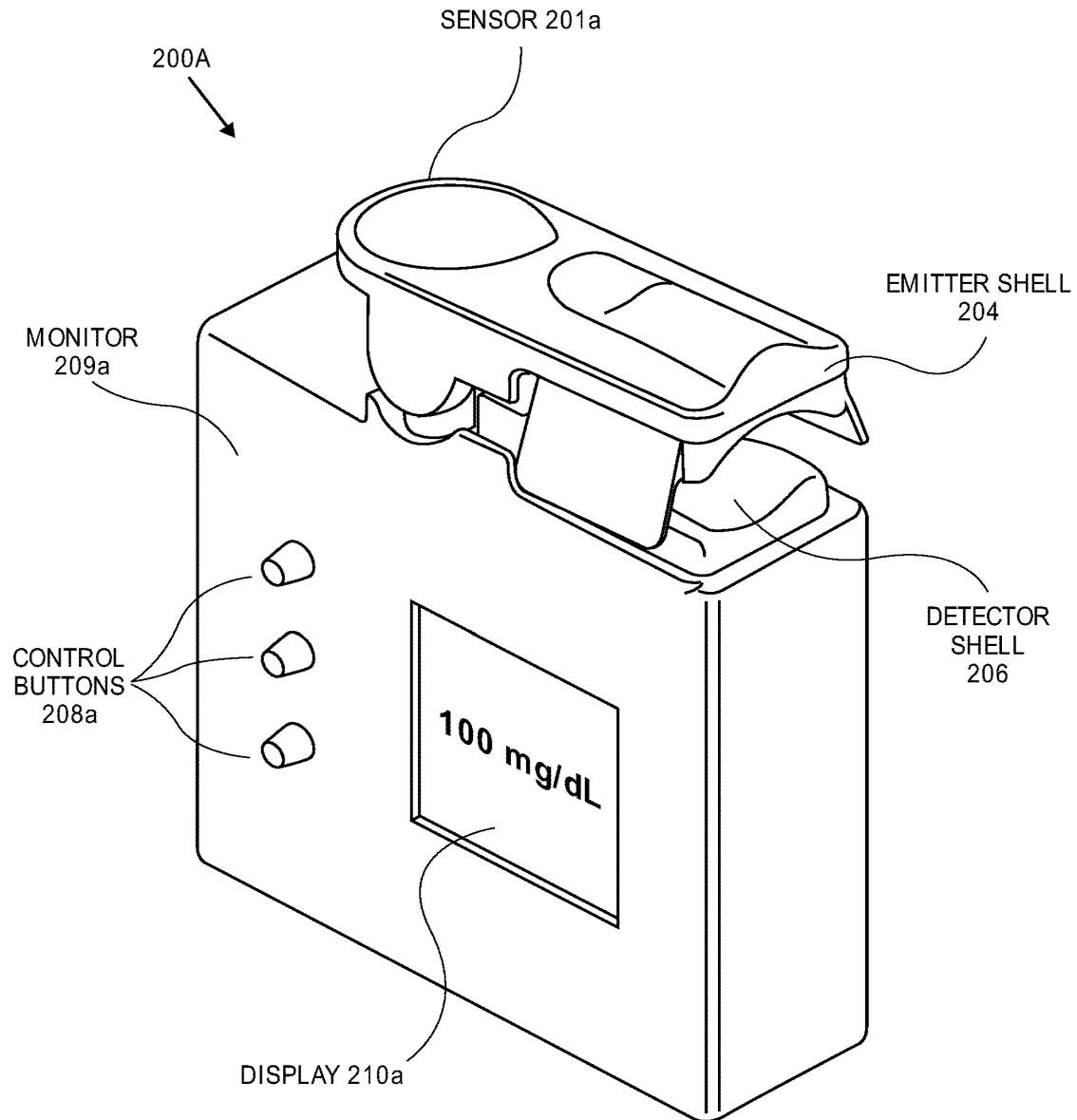


FIG. 2A

3/65

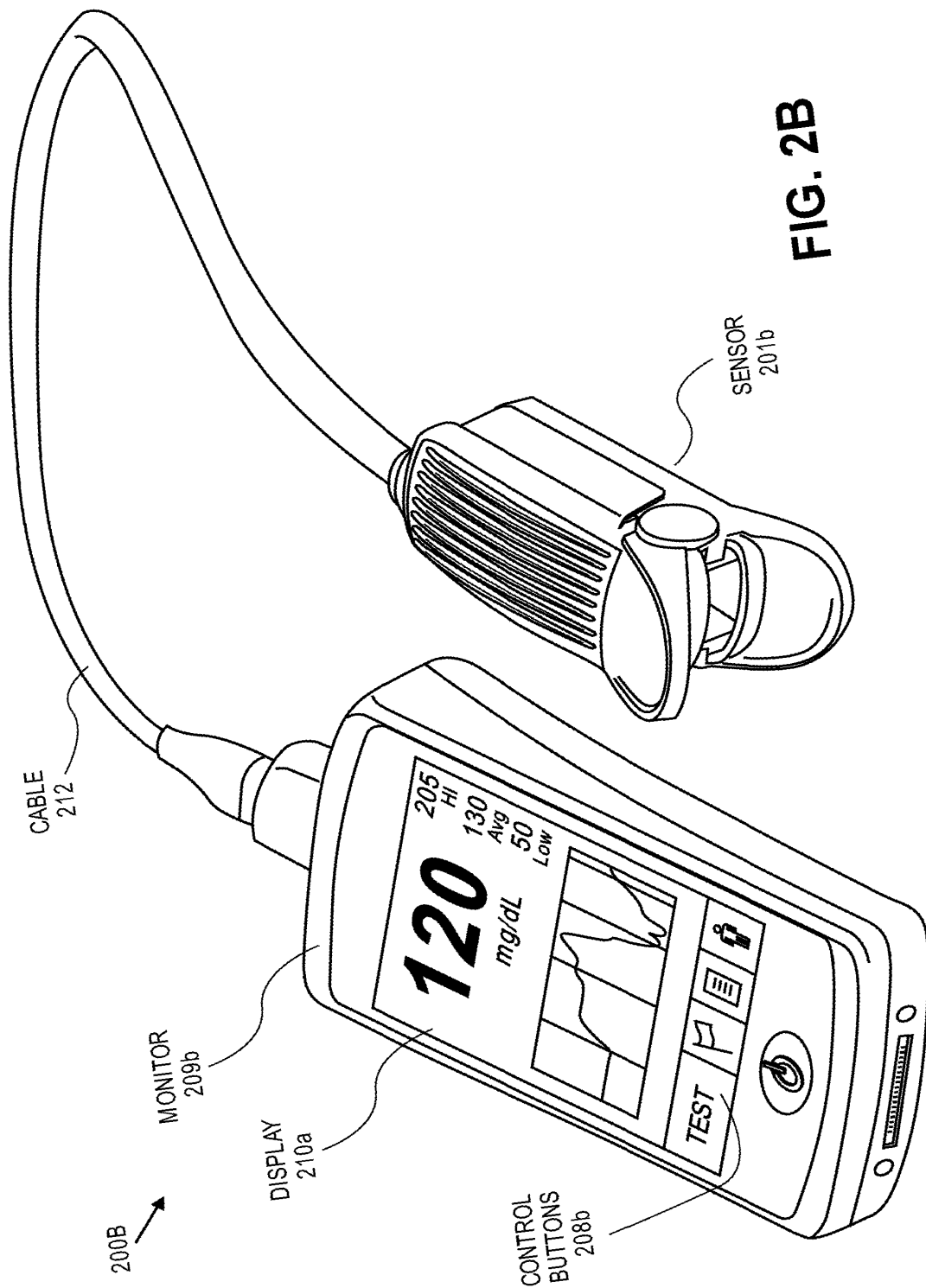


FIG. 2B

4/65

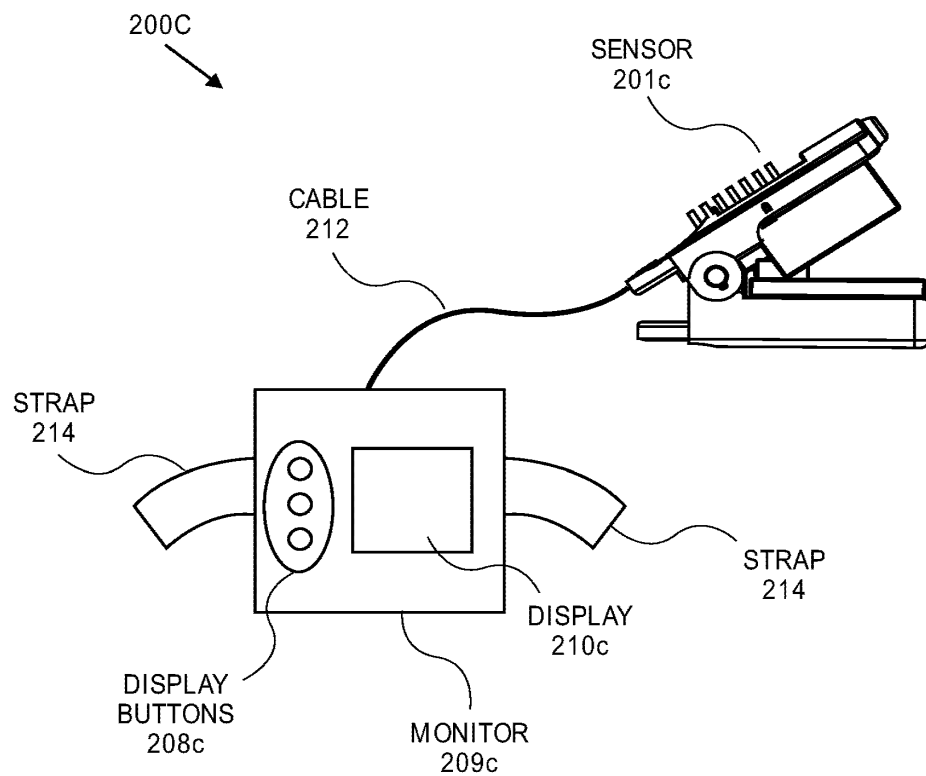


FIG. 2C

5/65

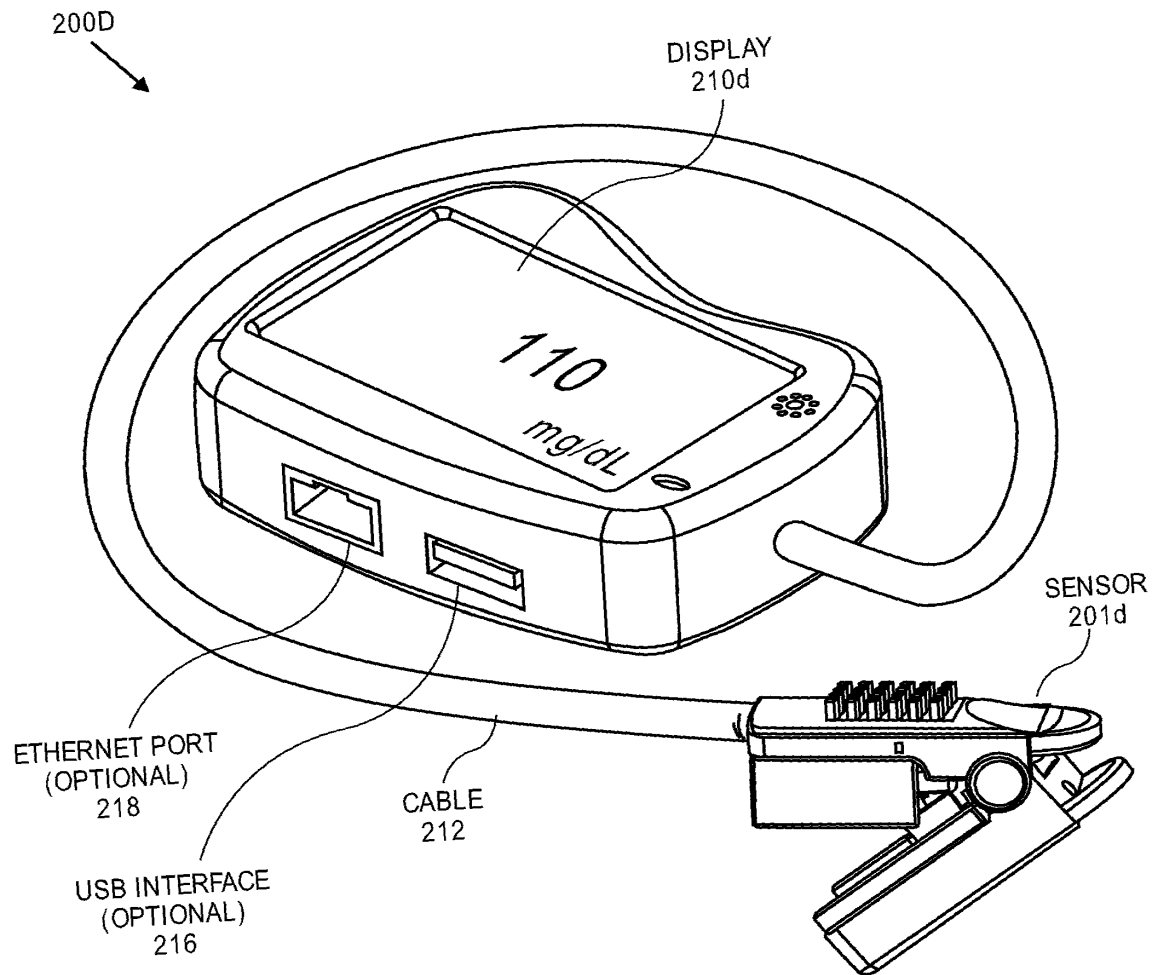


FIG. 2D

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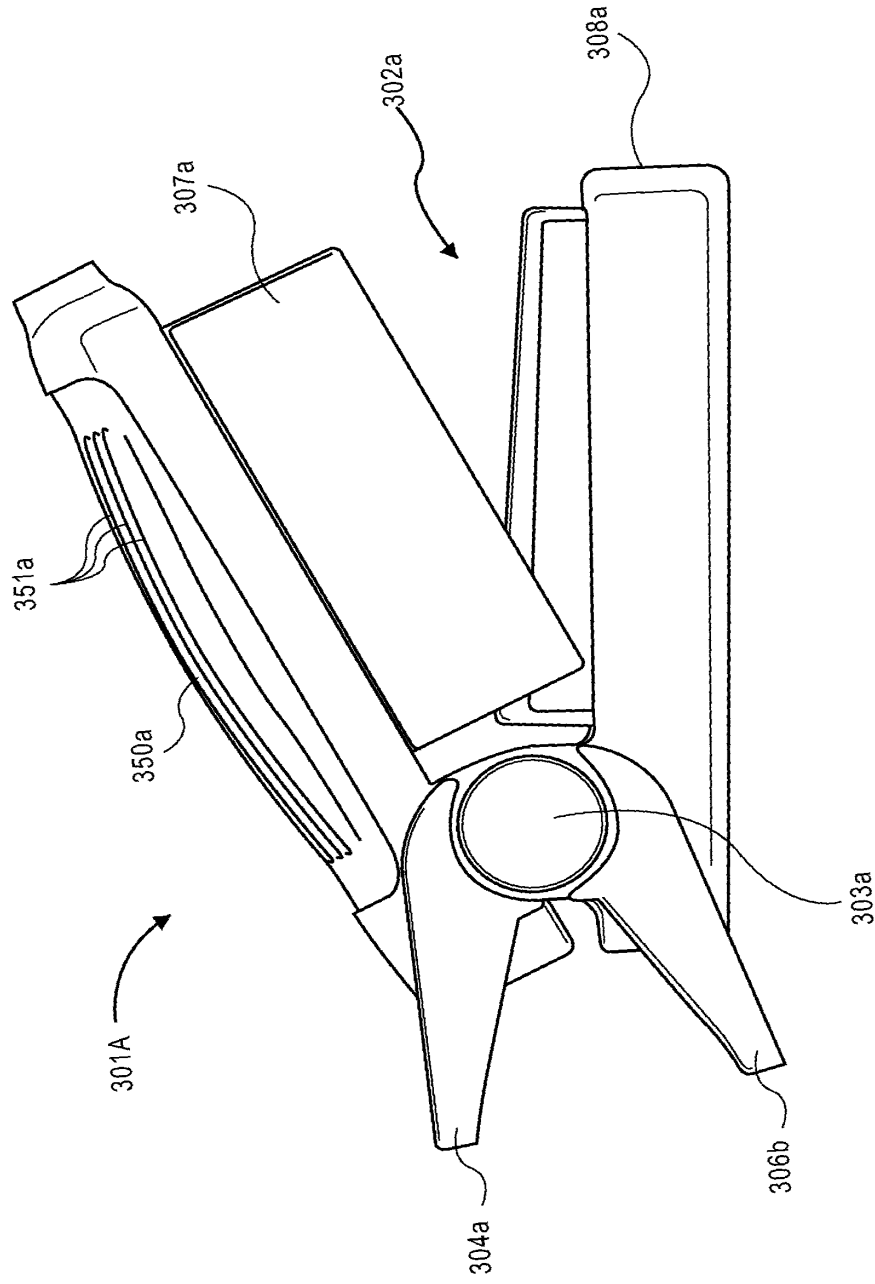


FIG. 3A

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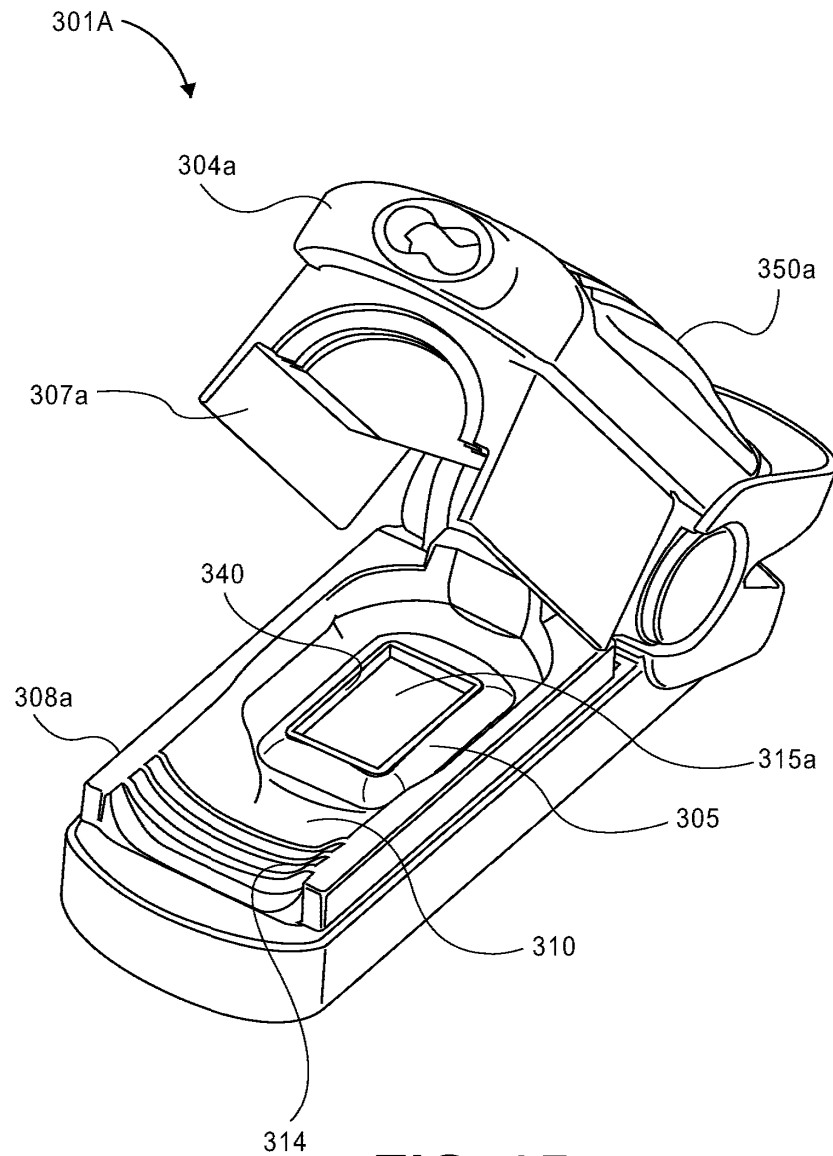


FIG. 3B

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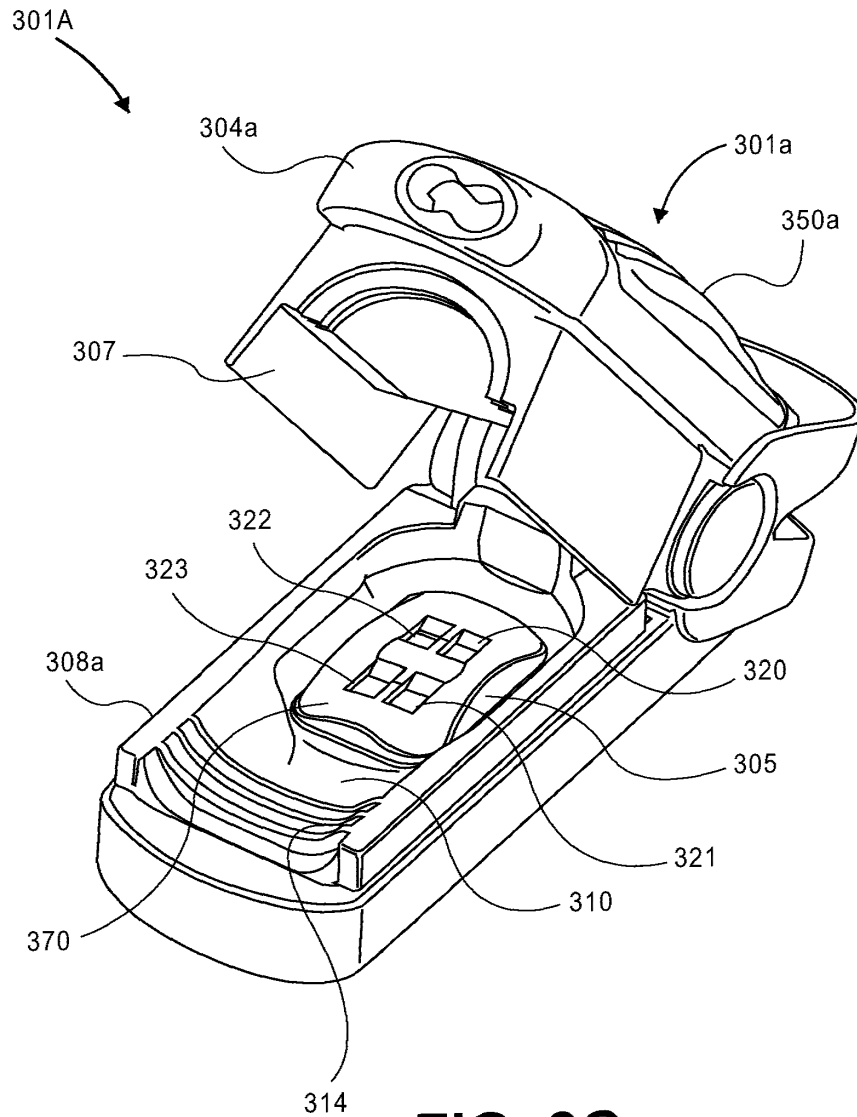


FIG. 3C

9/65

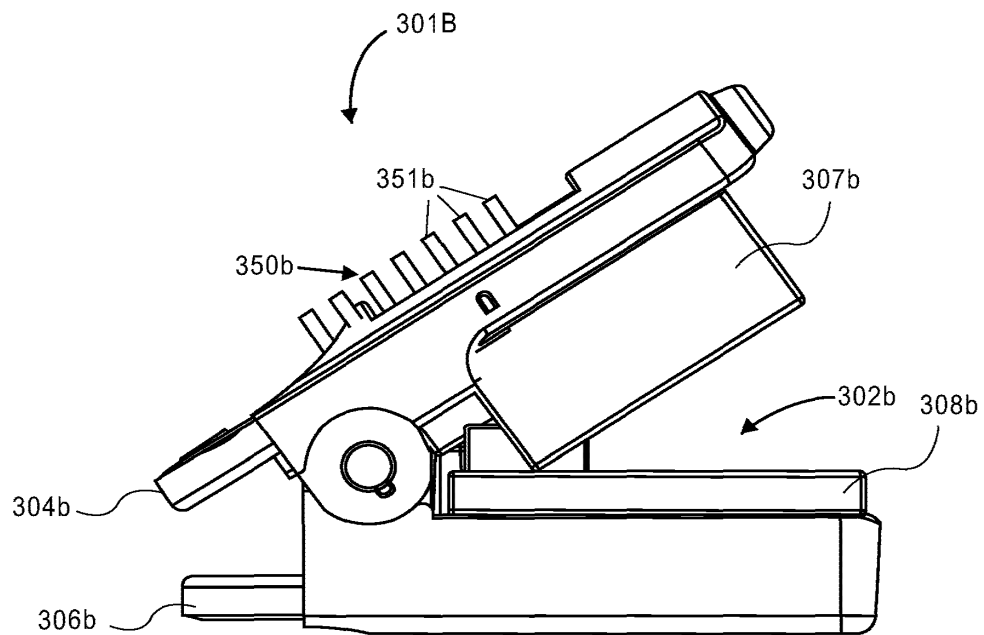


FIG. 3D

10/65

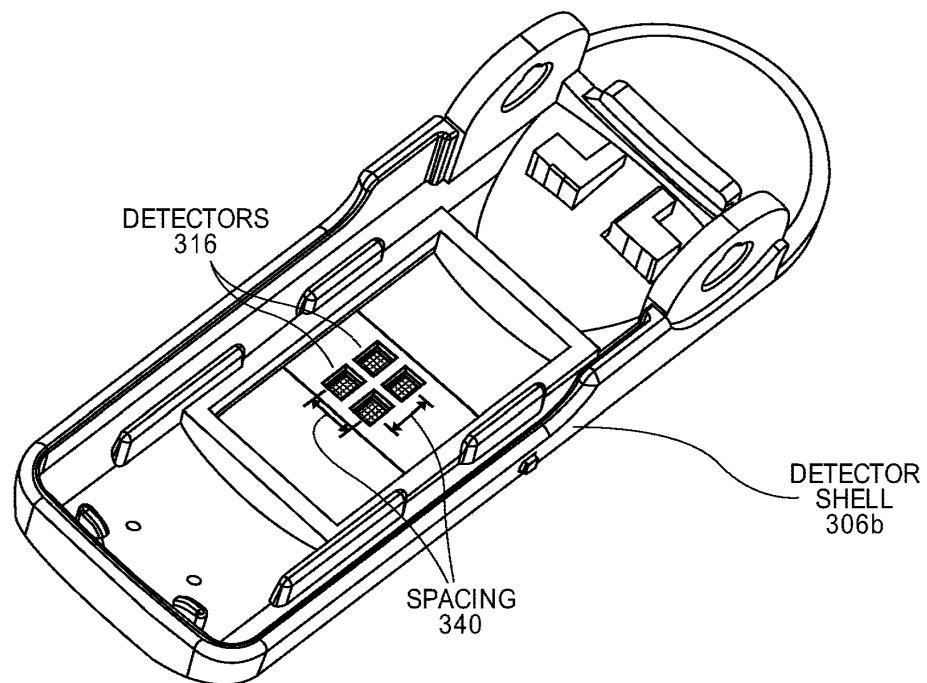


FIG. 3E

11/65

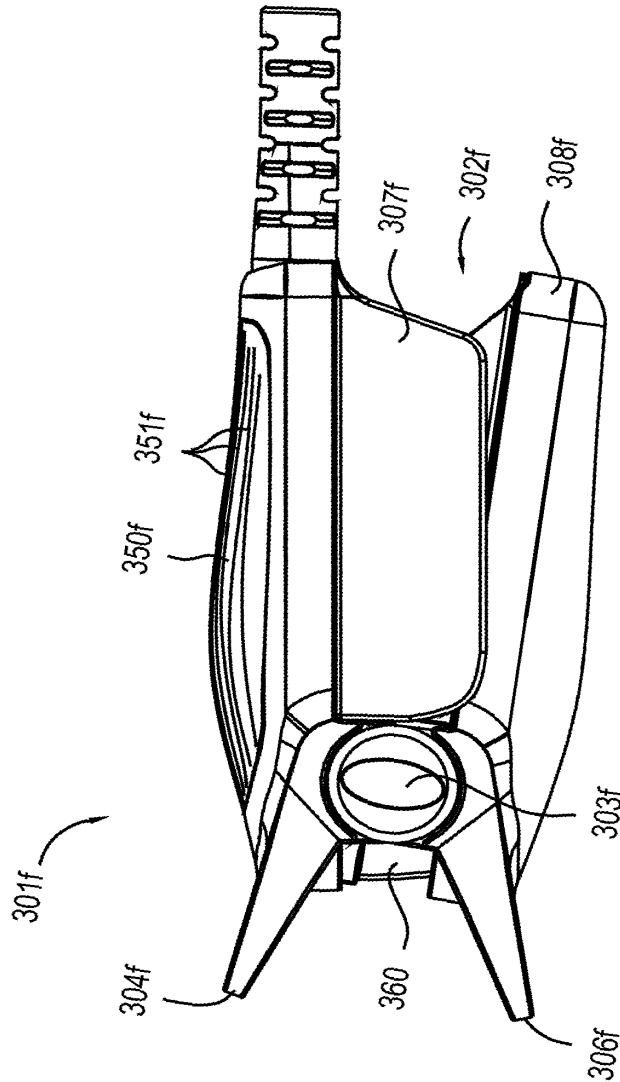


FIG. 3F

12/65

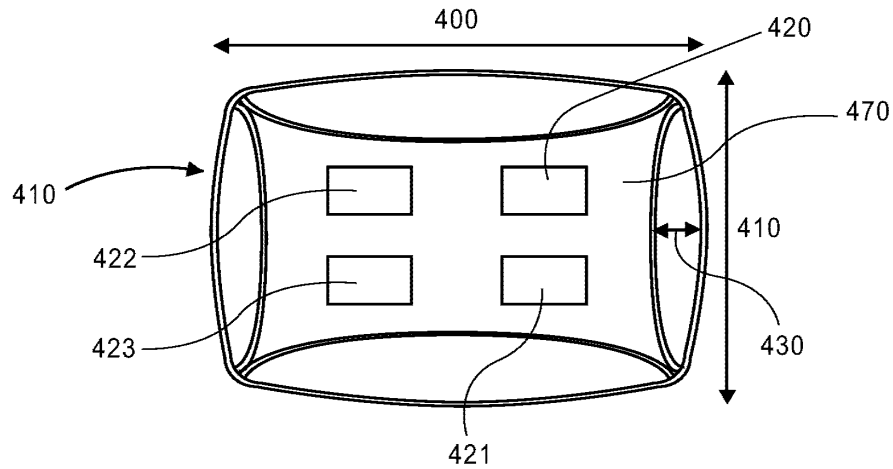


FIG. 4A

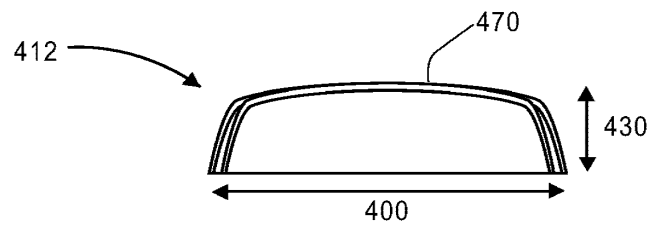


FIG. 4B

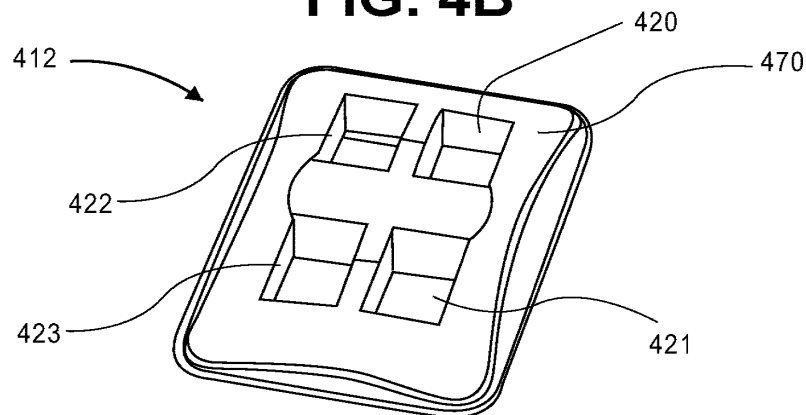


FIG. 4C

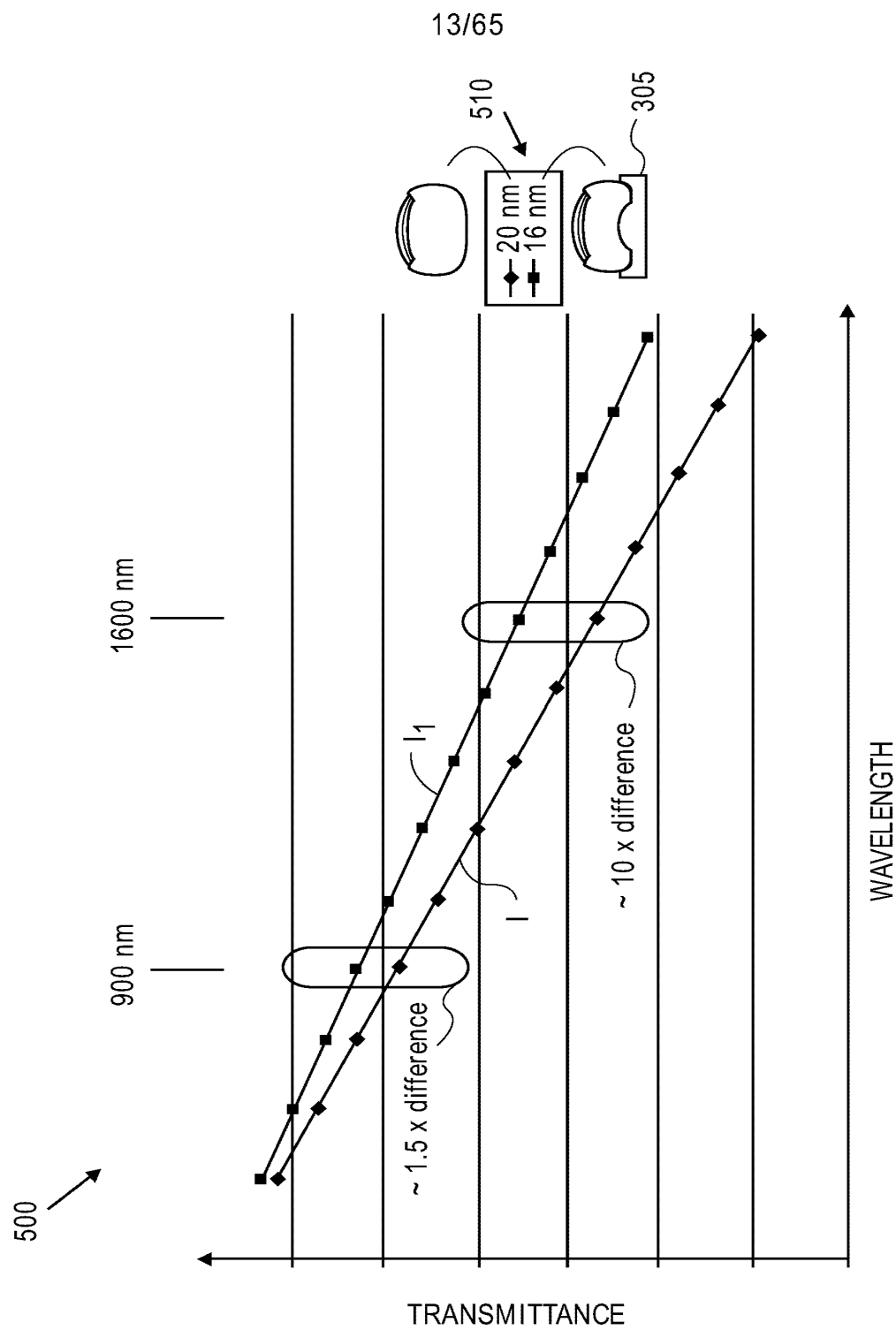


FIG. 5

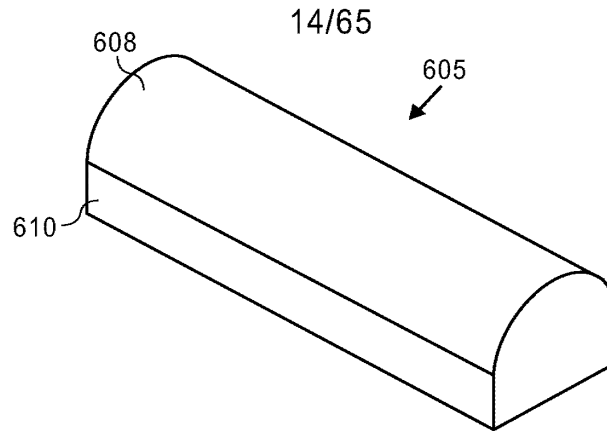


FIG. 6A

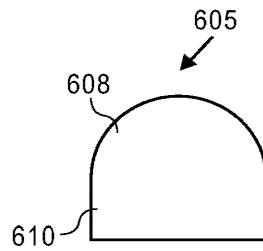


FIG. 6B

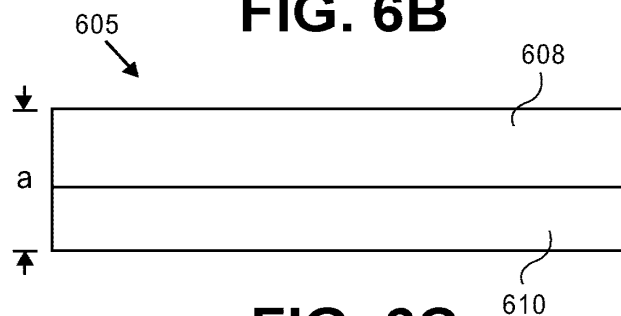


FIG. 6C

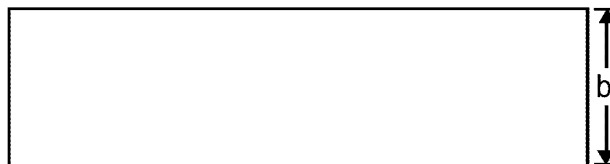


FIG. 6D

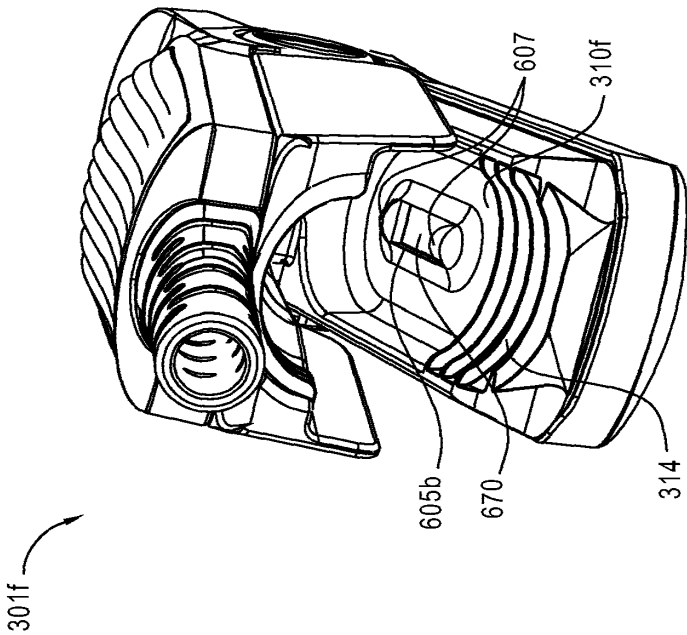
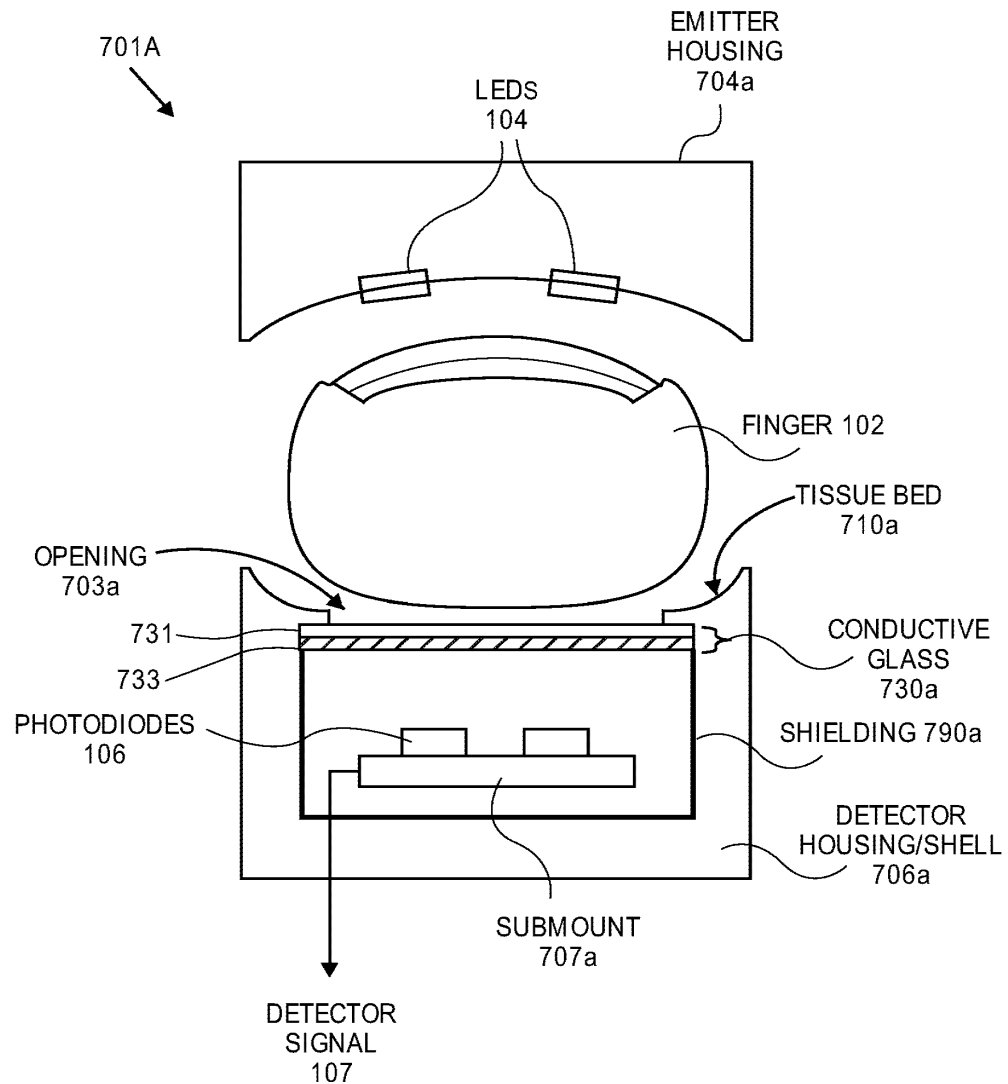


FIG. 6E

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**FIG. 7A**

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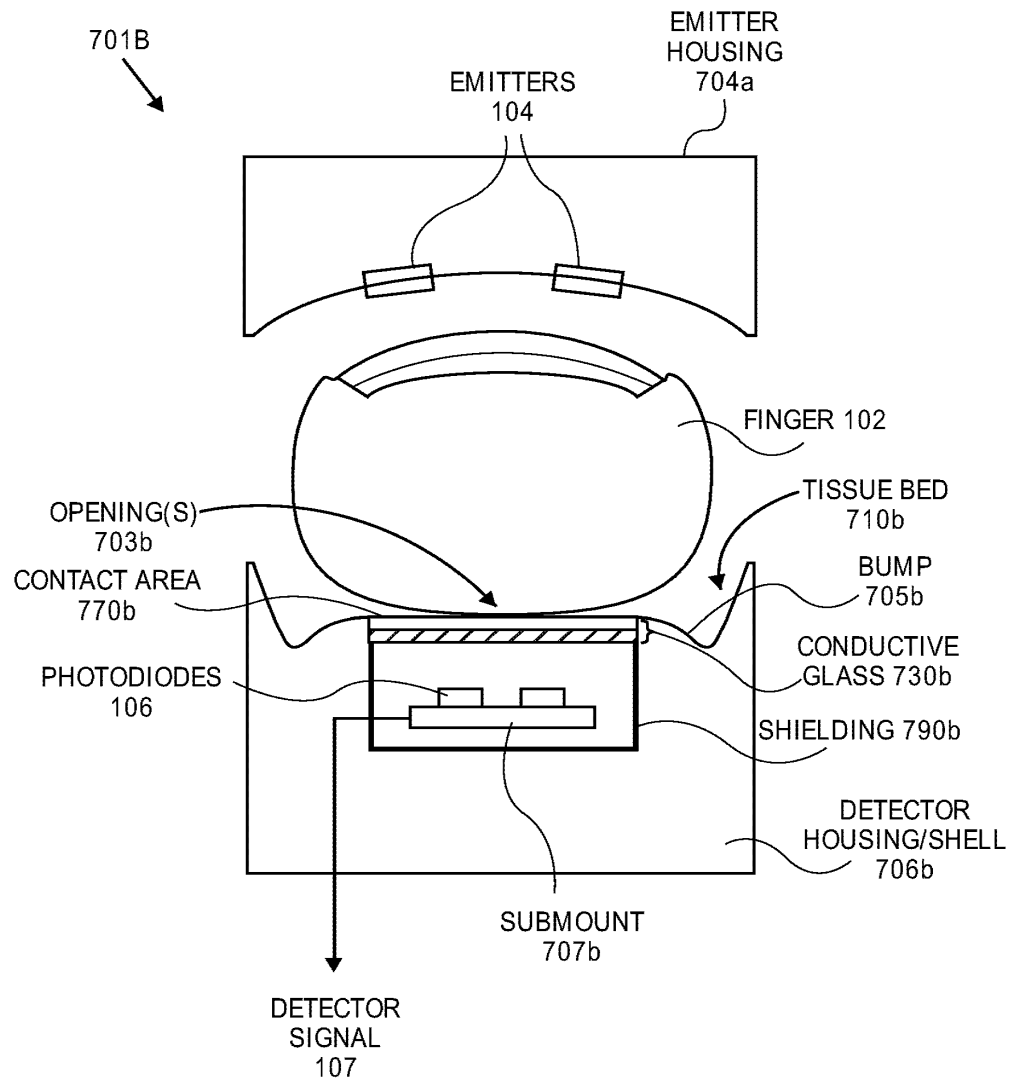


FIG. 7B

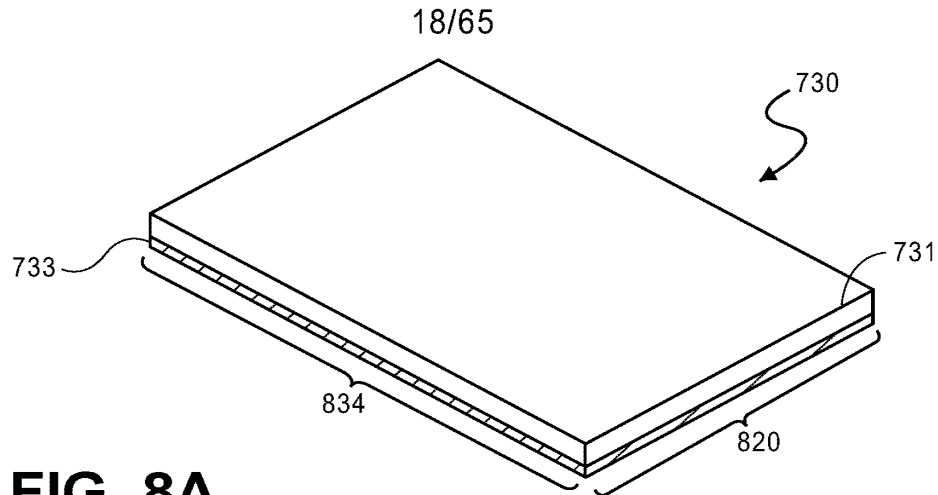


FIG. 8A

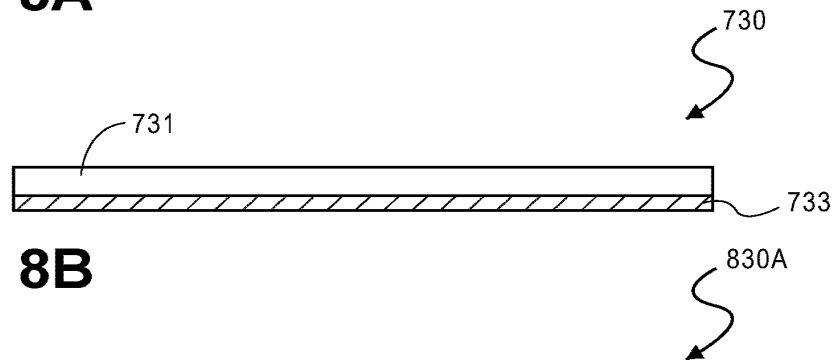


FIG. 8B

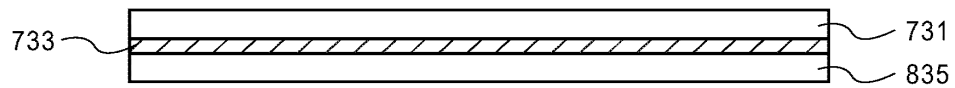


FIG. 8C

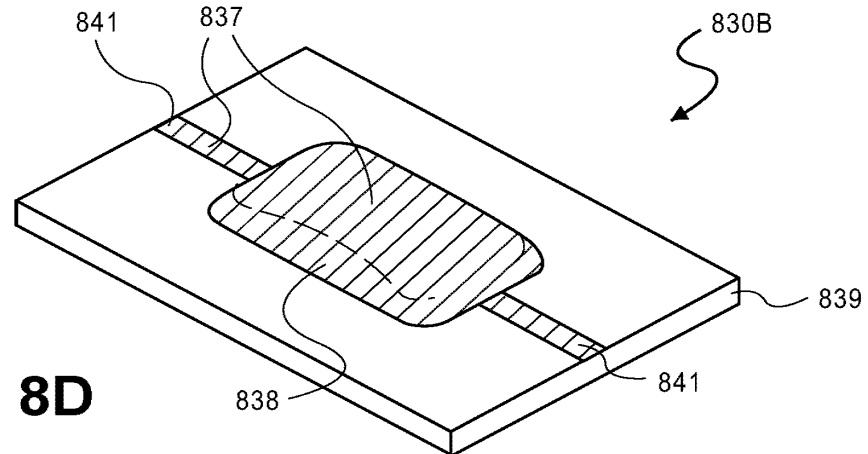
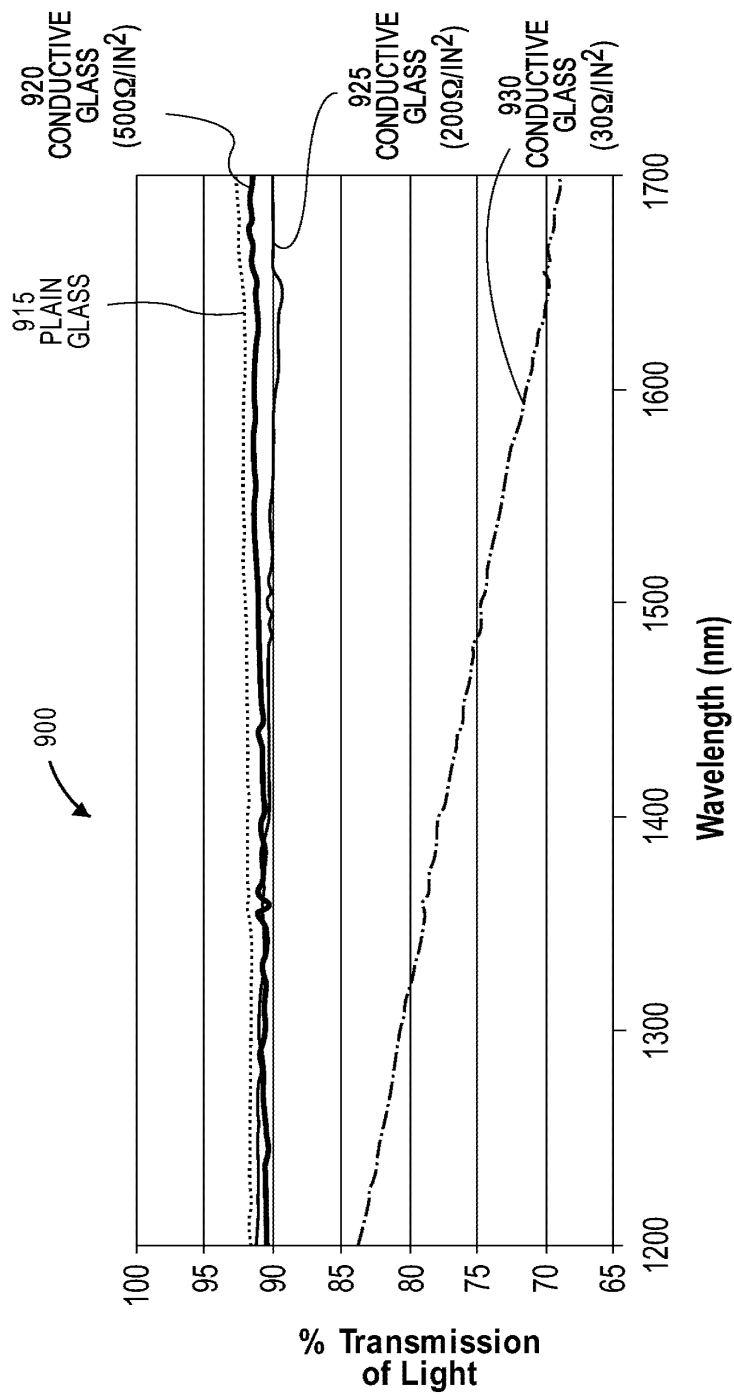


FIG. 8D



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FIG. 9

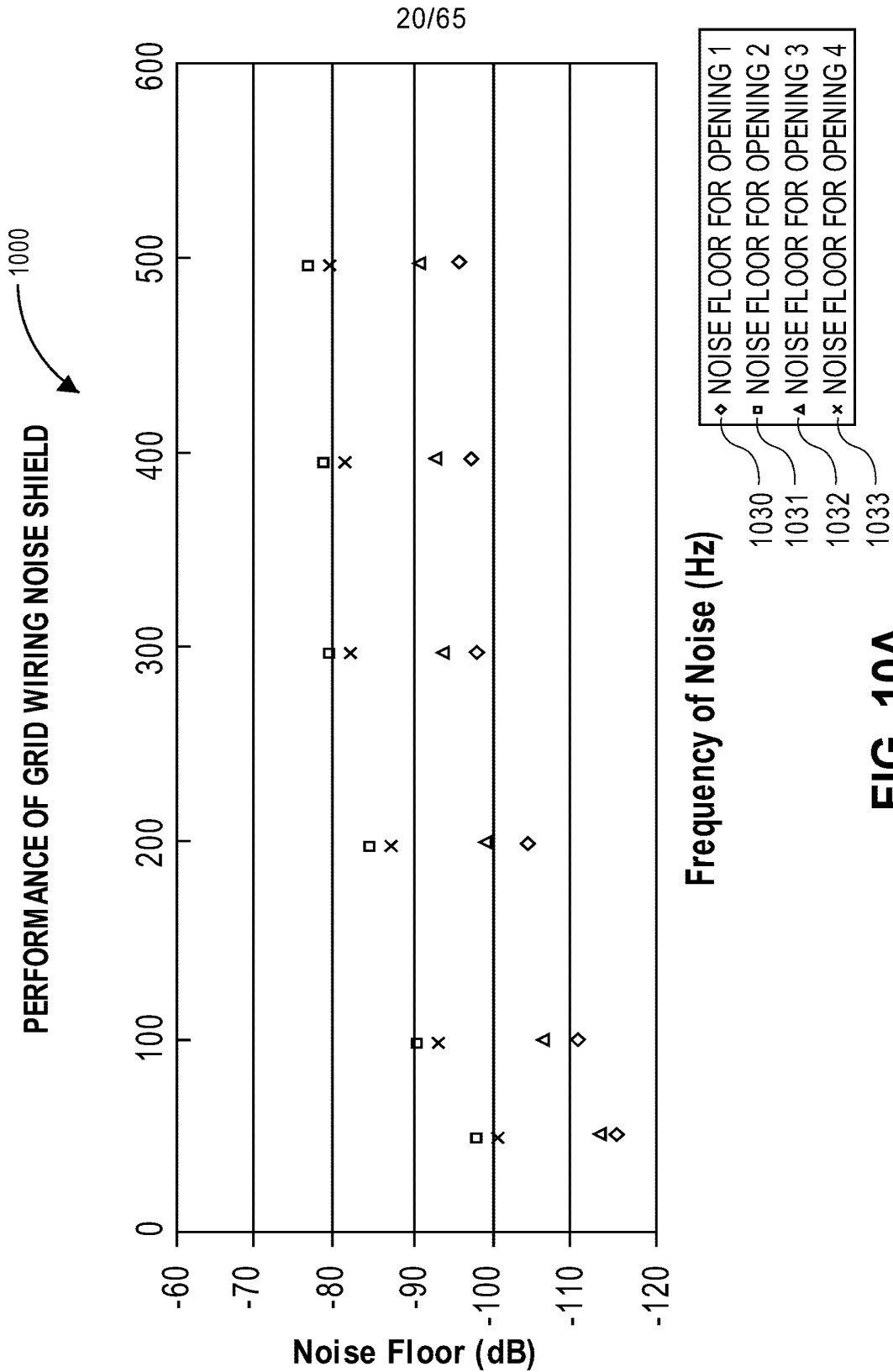
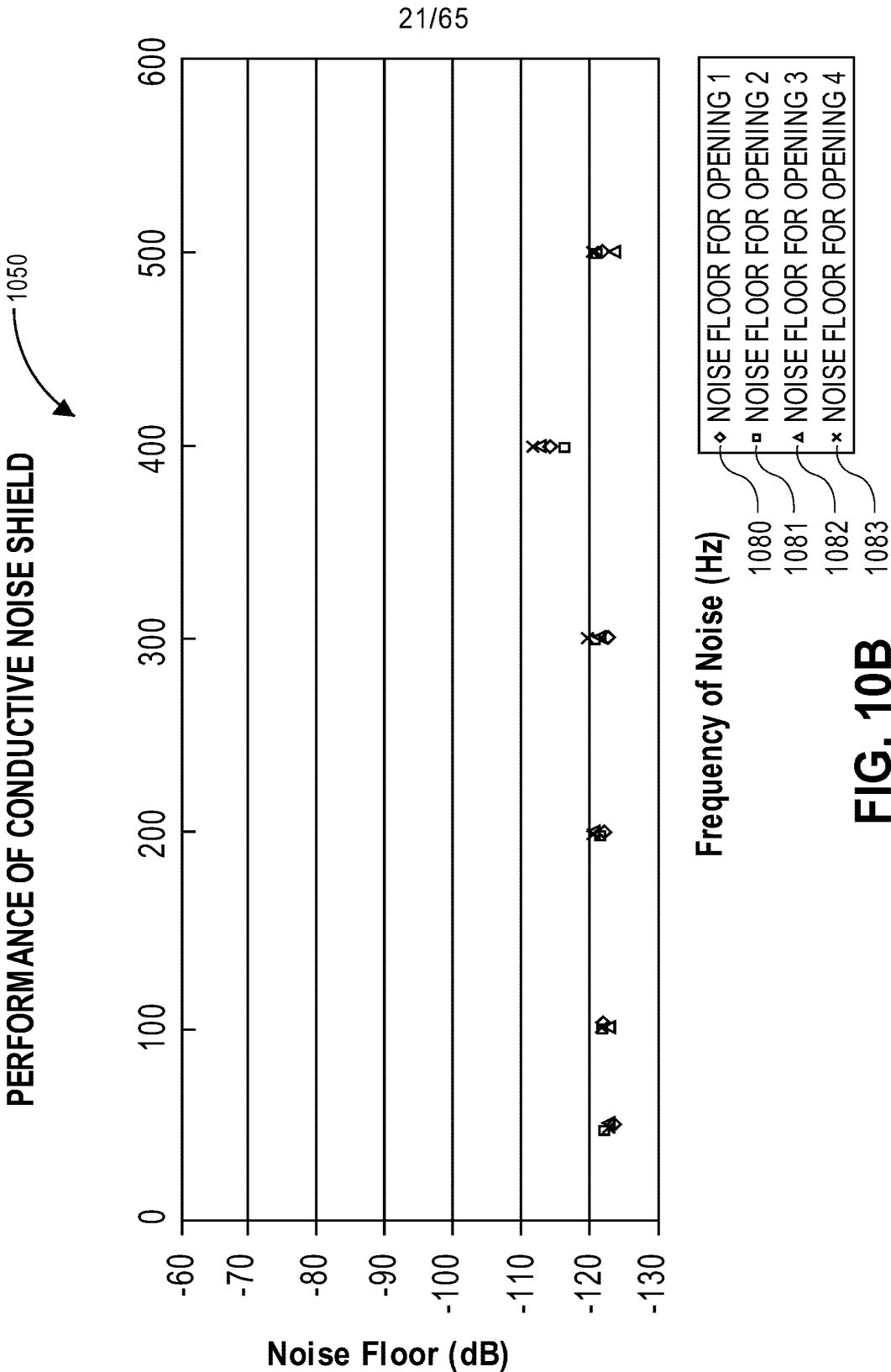
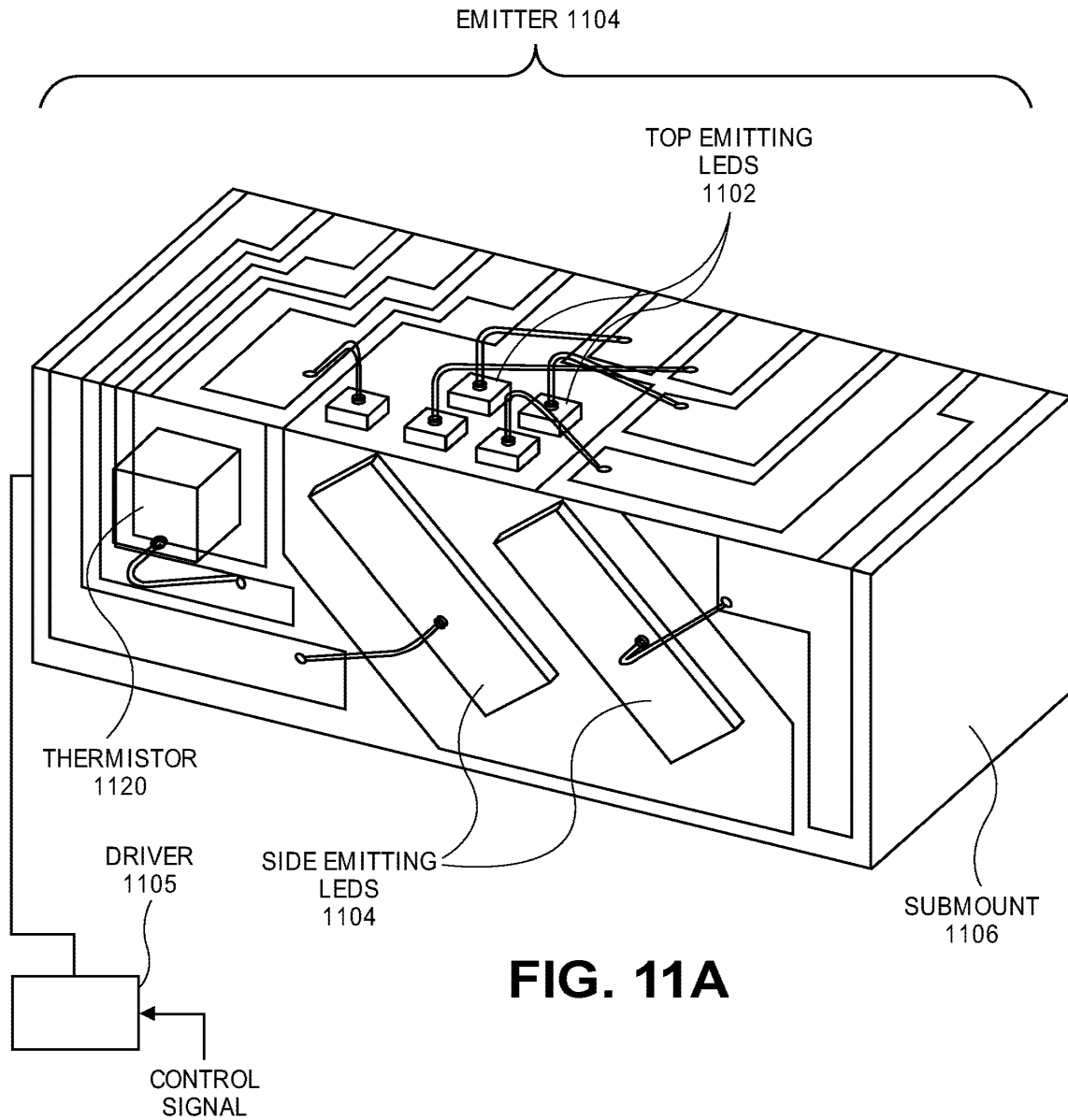


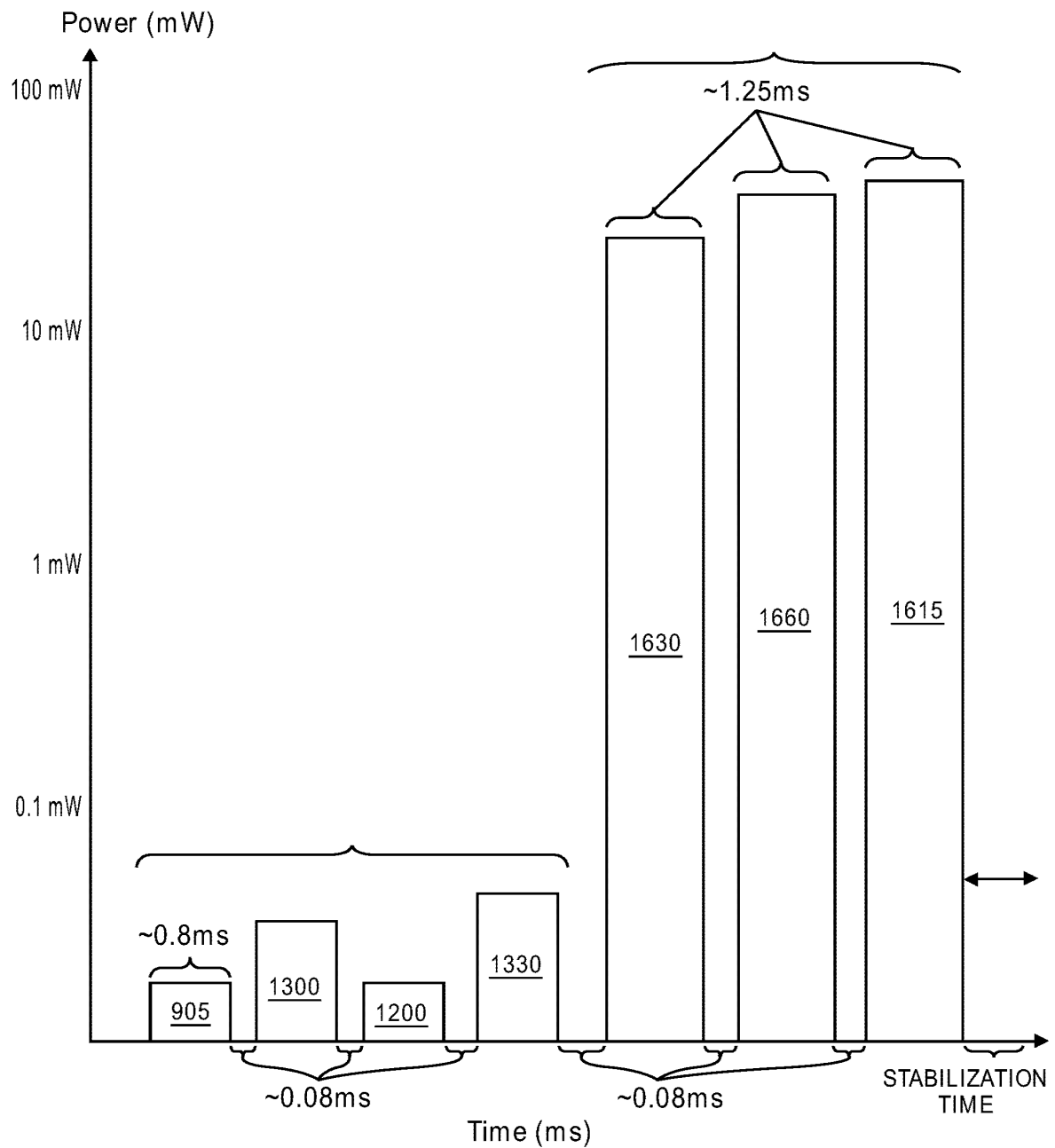
FIG. 10A



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**FIG. 11B**

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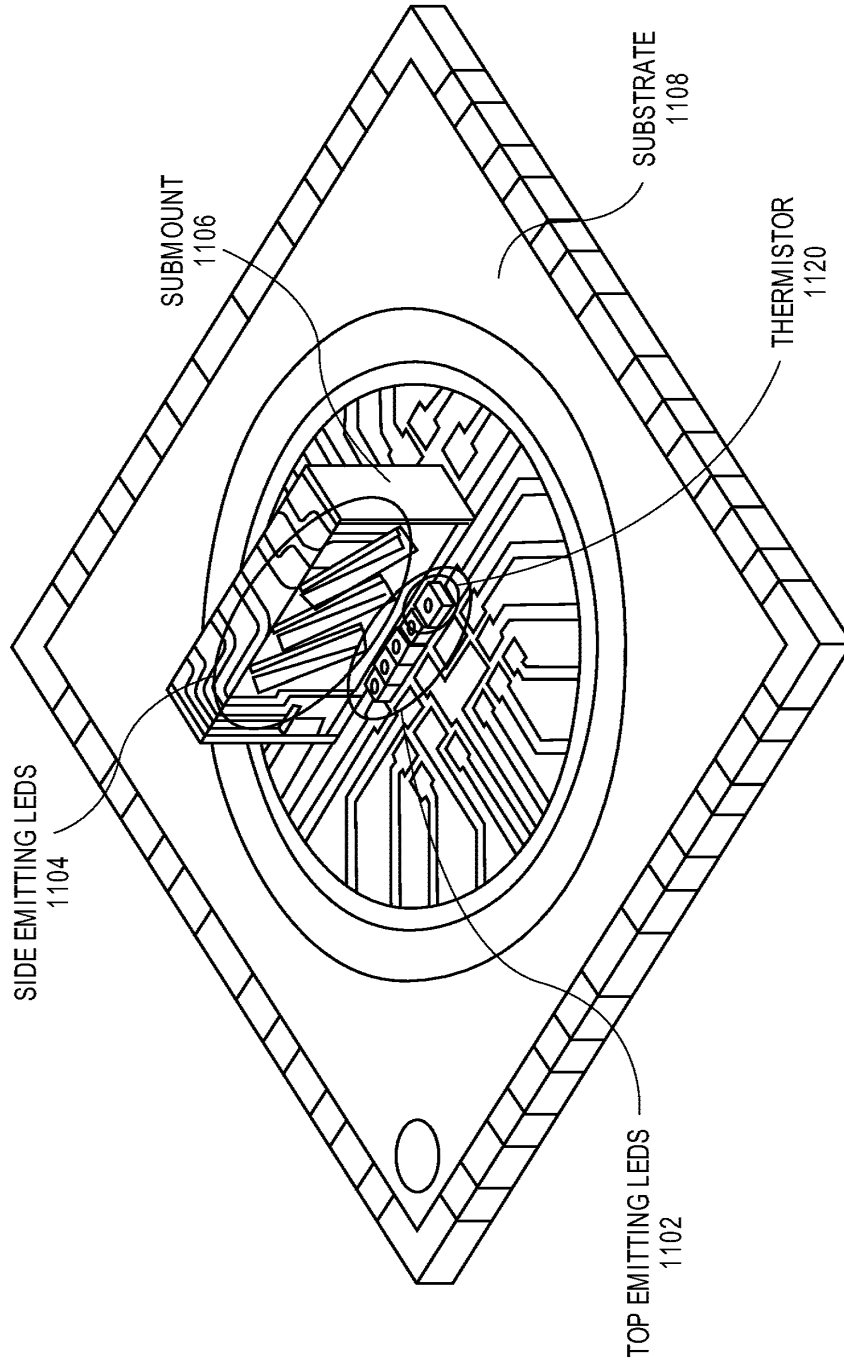


FIG. 11C

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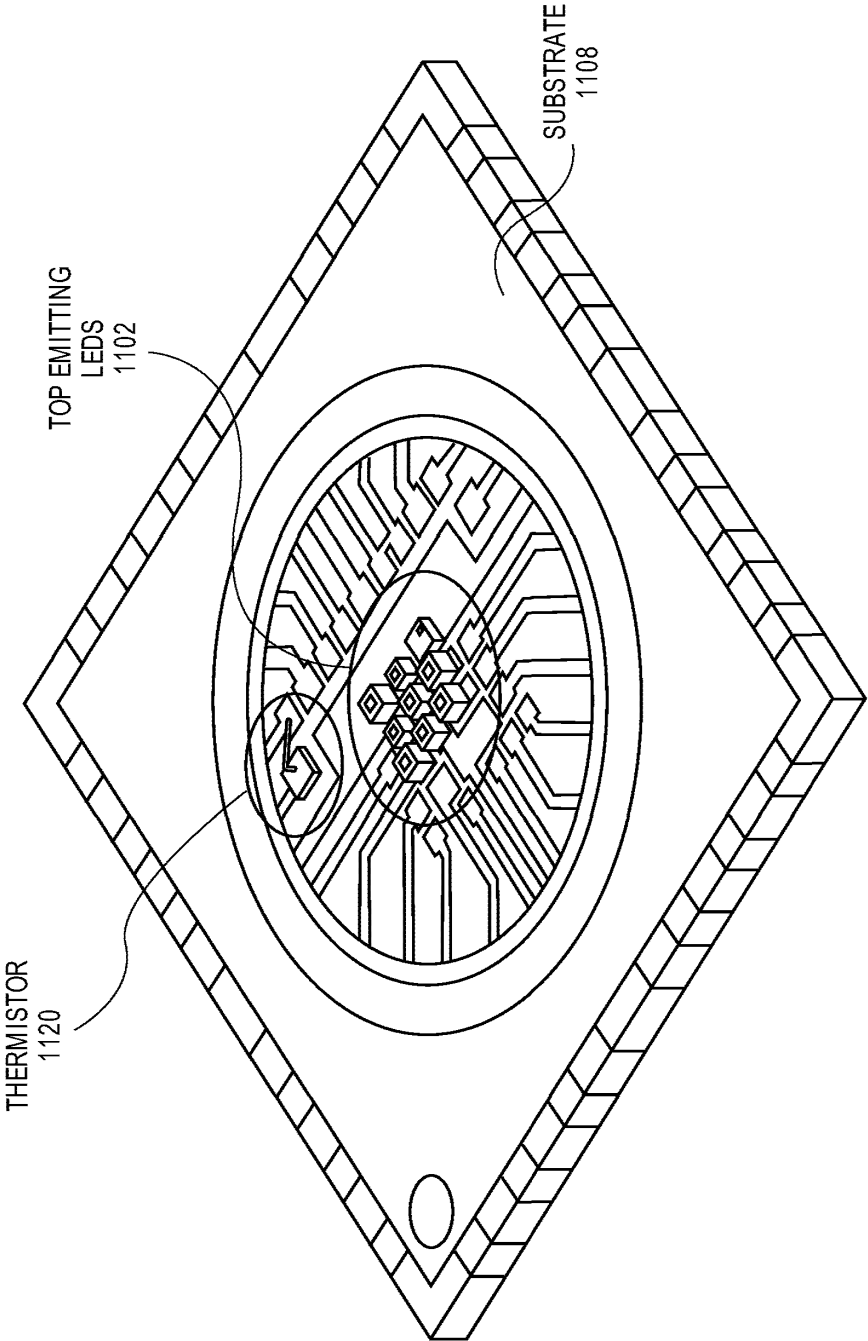


FIG. 11D

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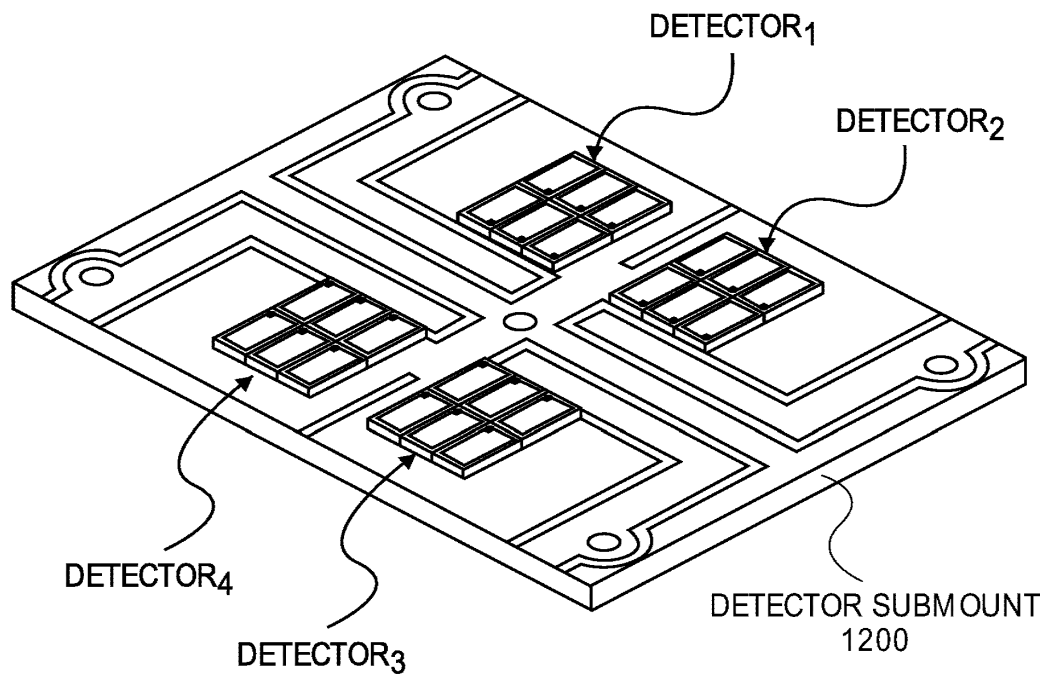


FIG. 12A

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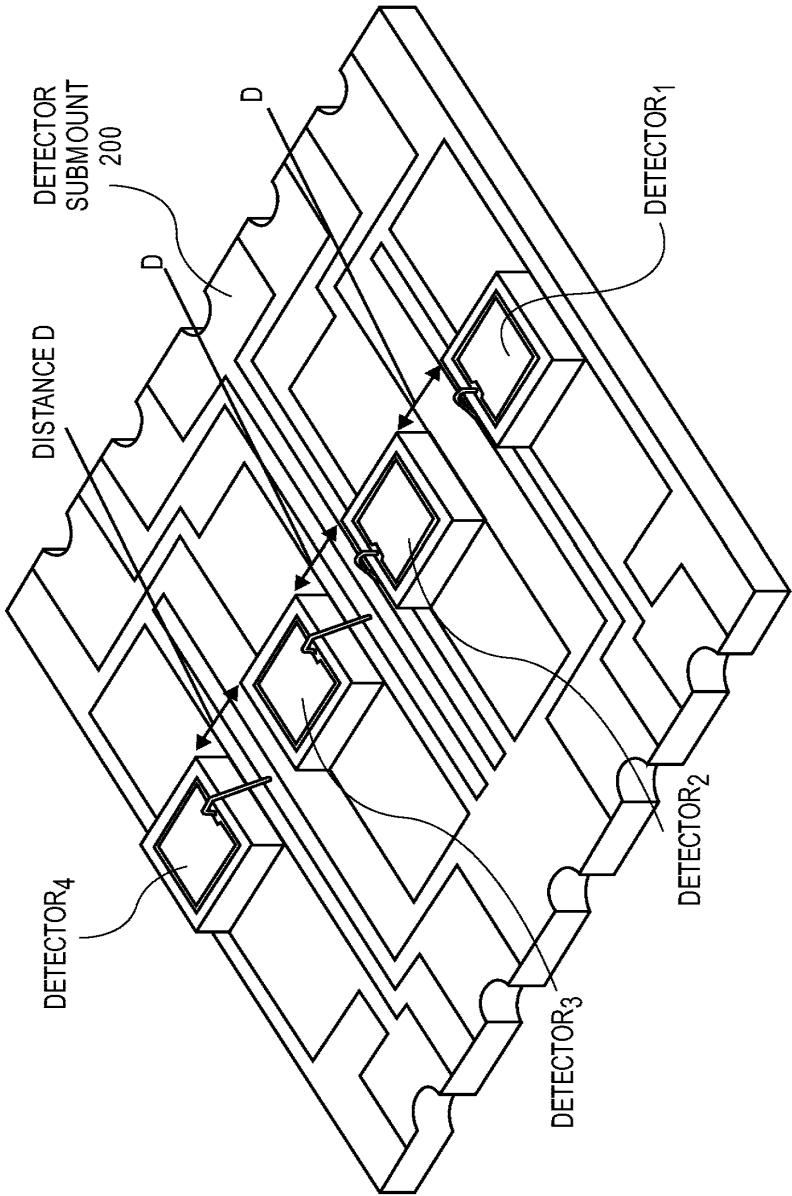


FIG. 12B

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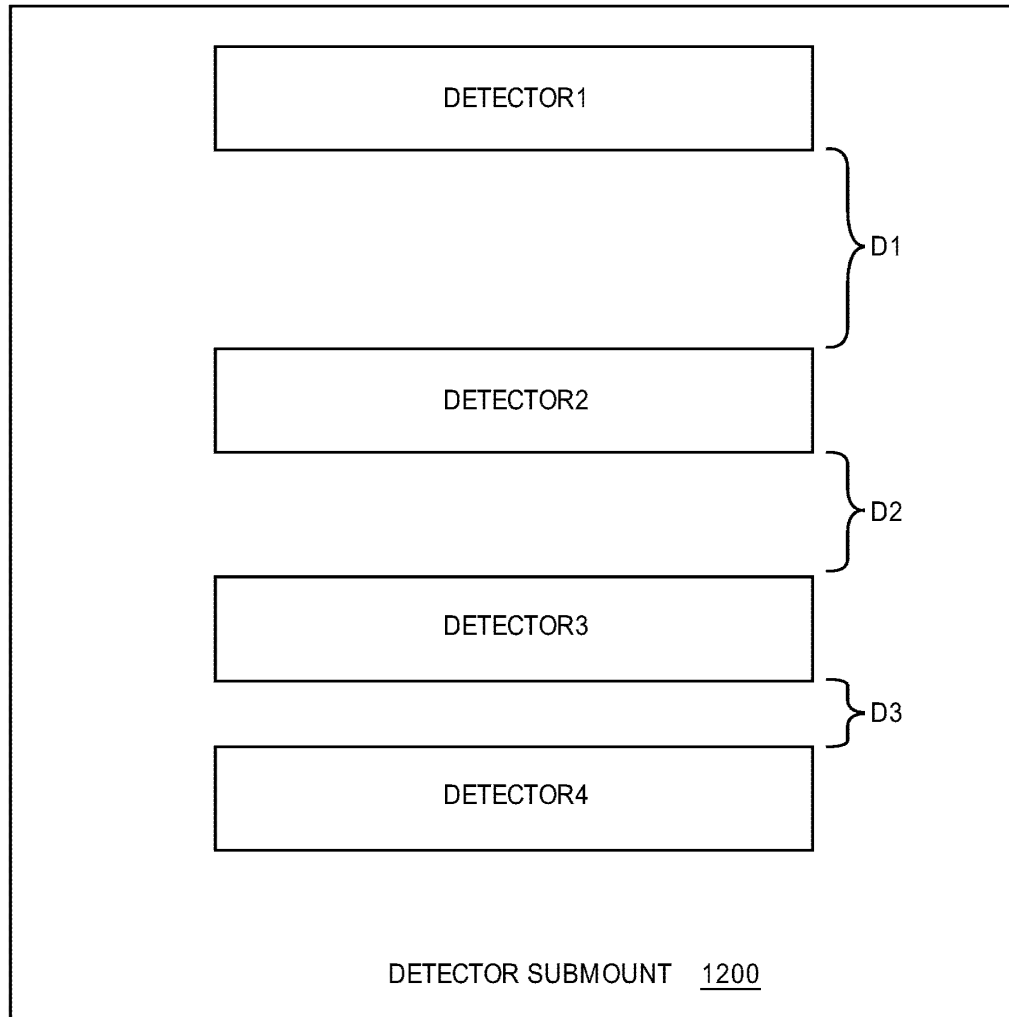


FIG. 12C

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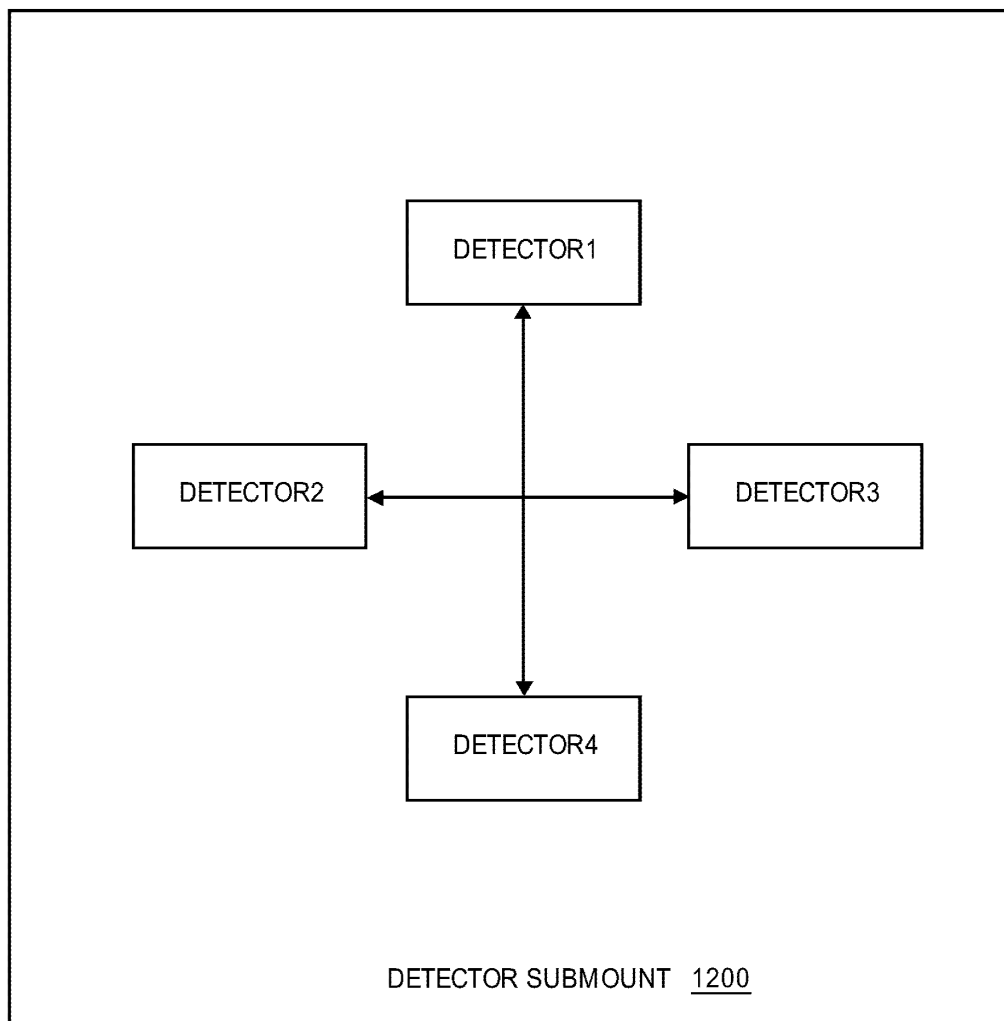


FIG. 12D

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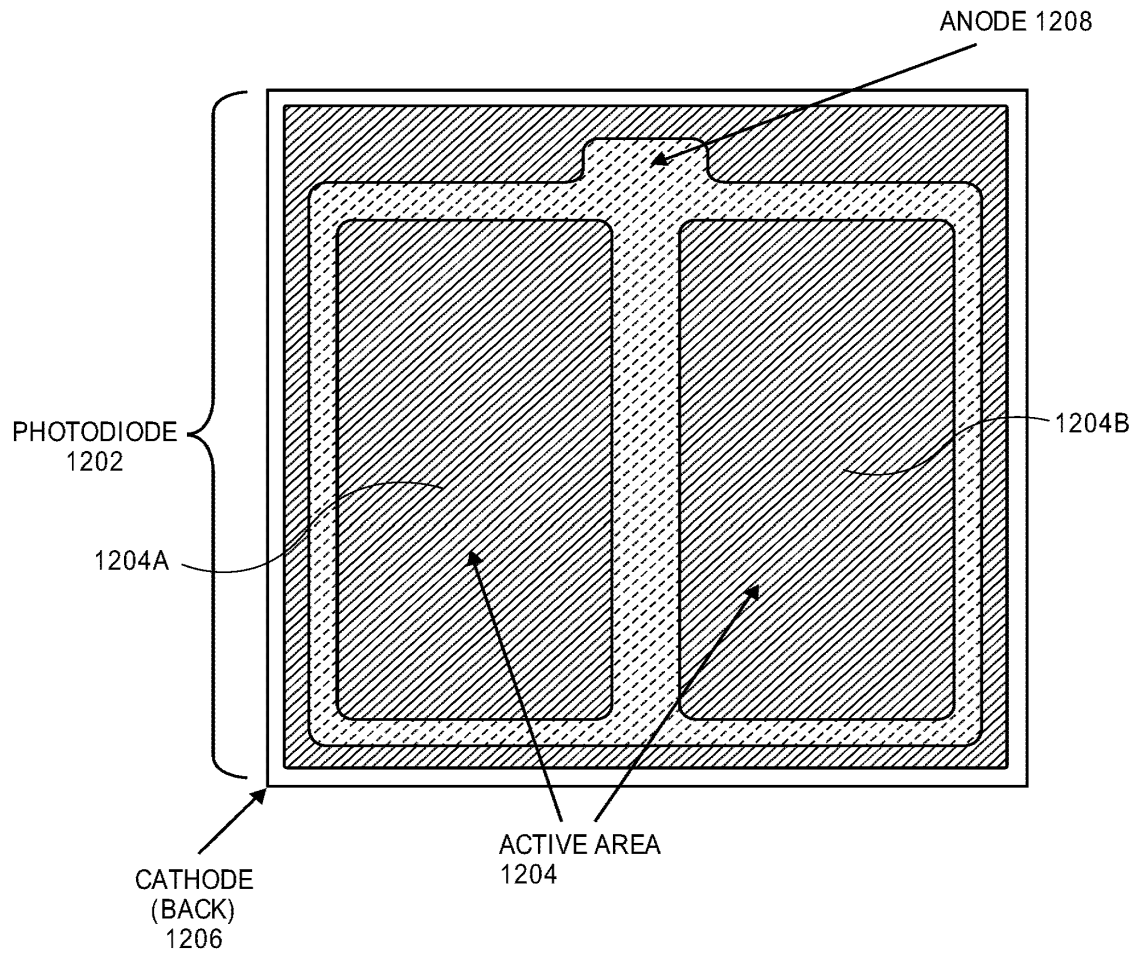


FIG. 12E

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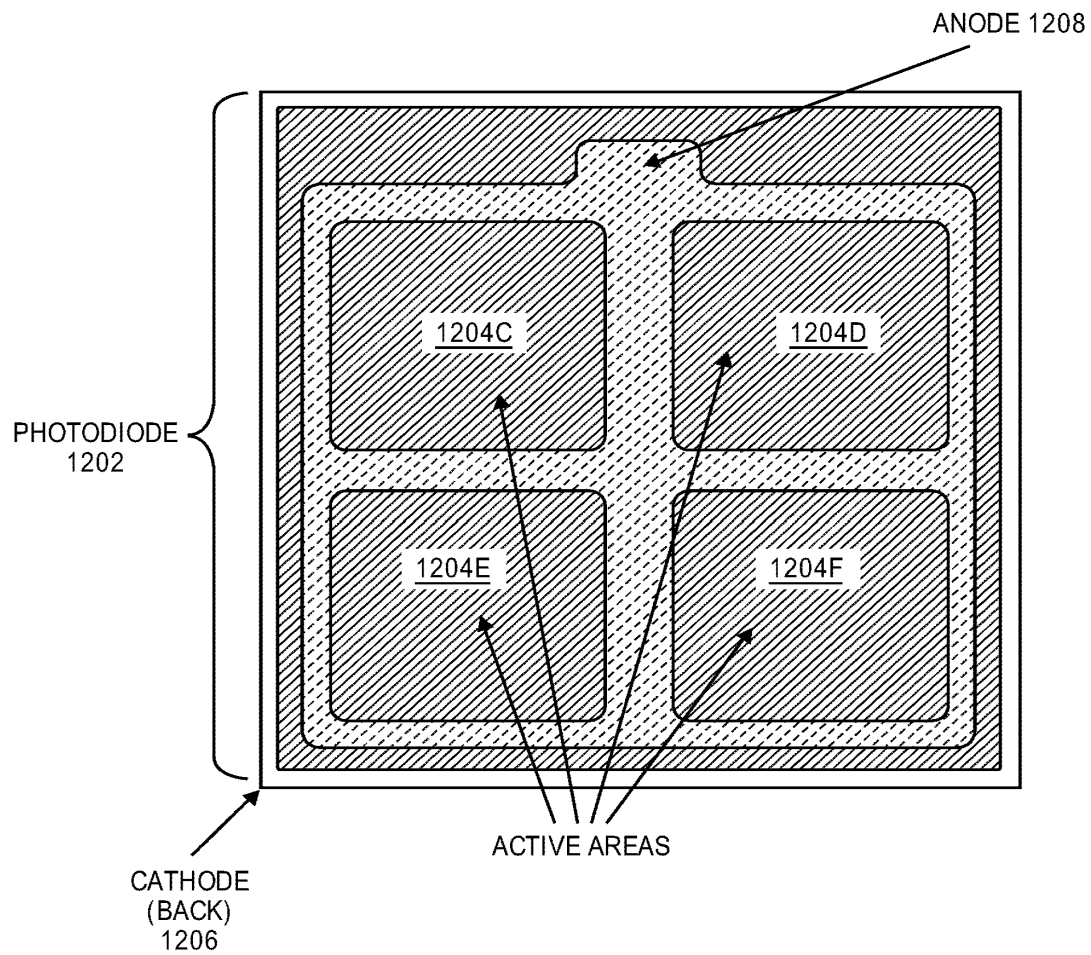


FIG. 12F

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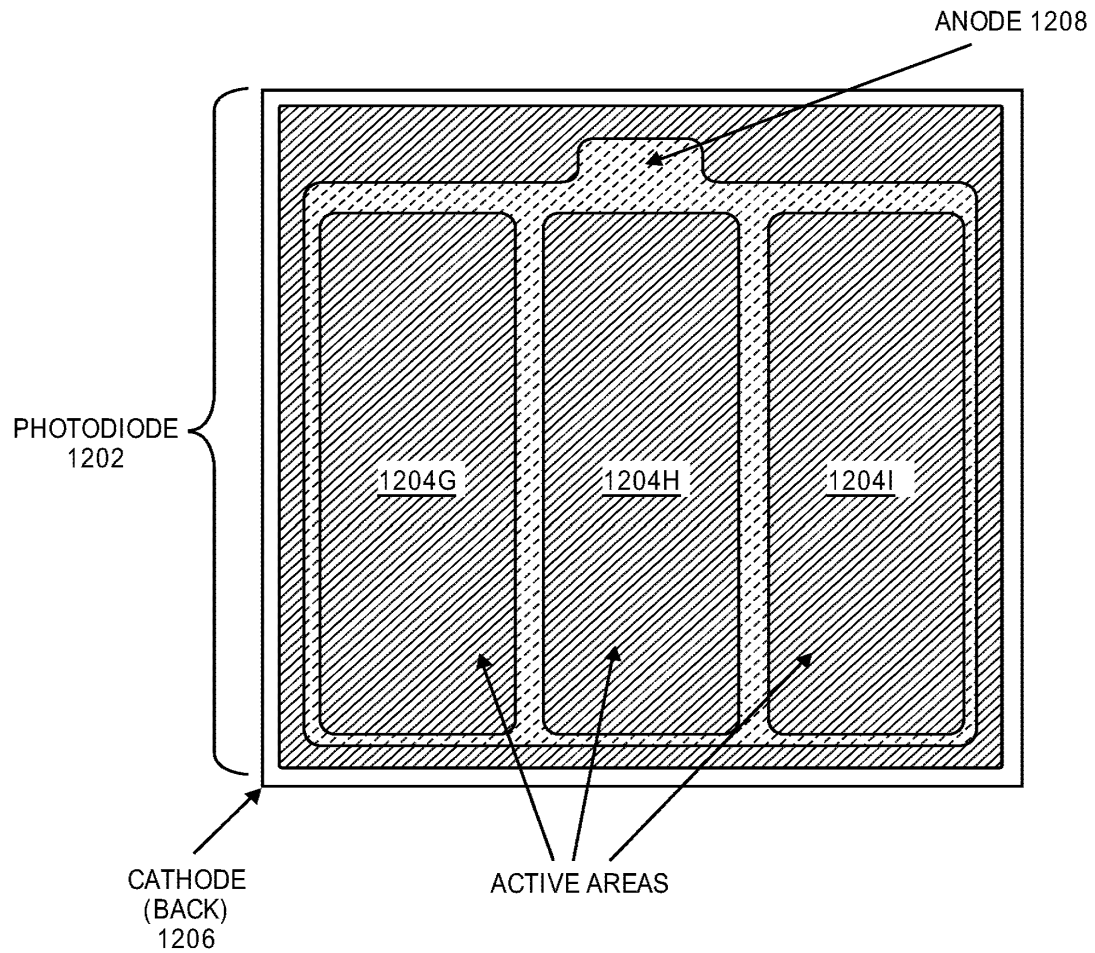


FIG. 12G

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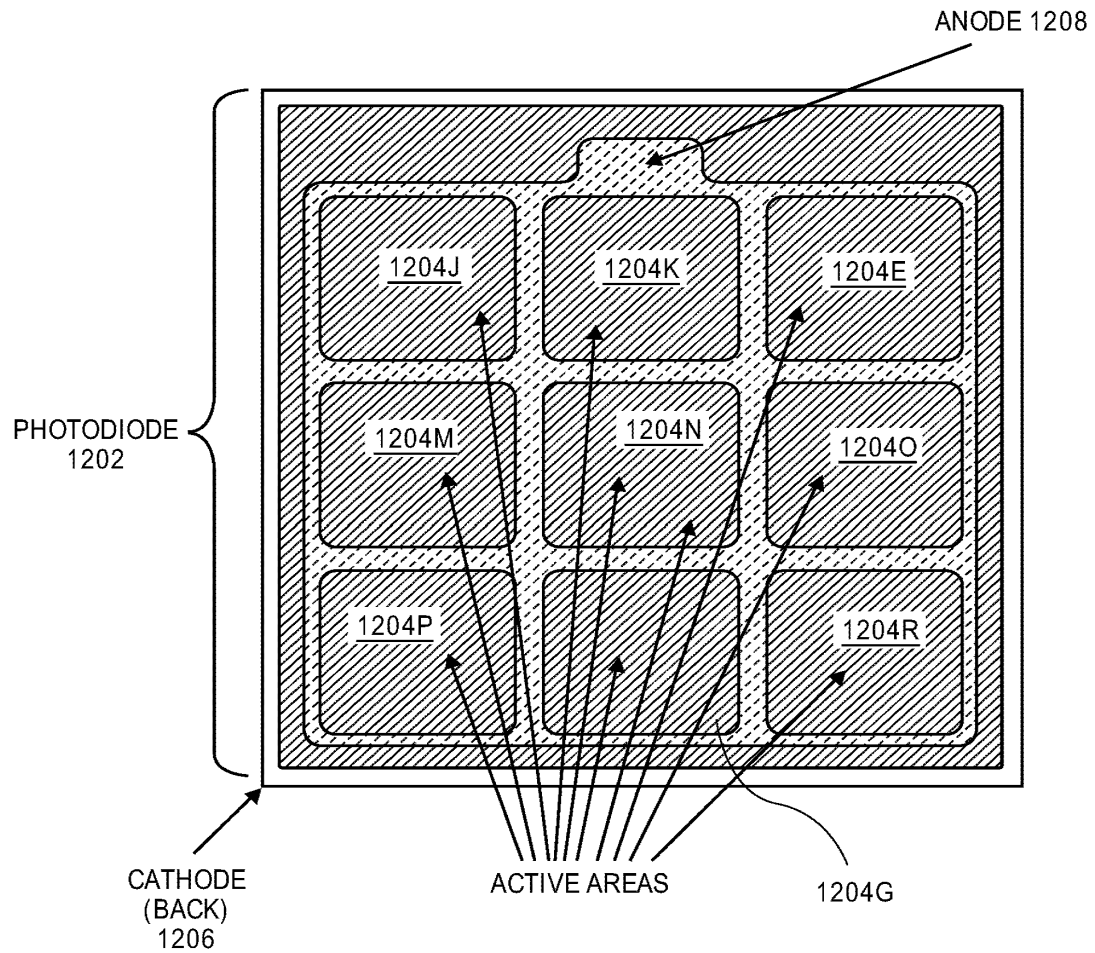
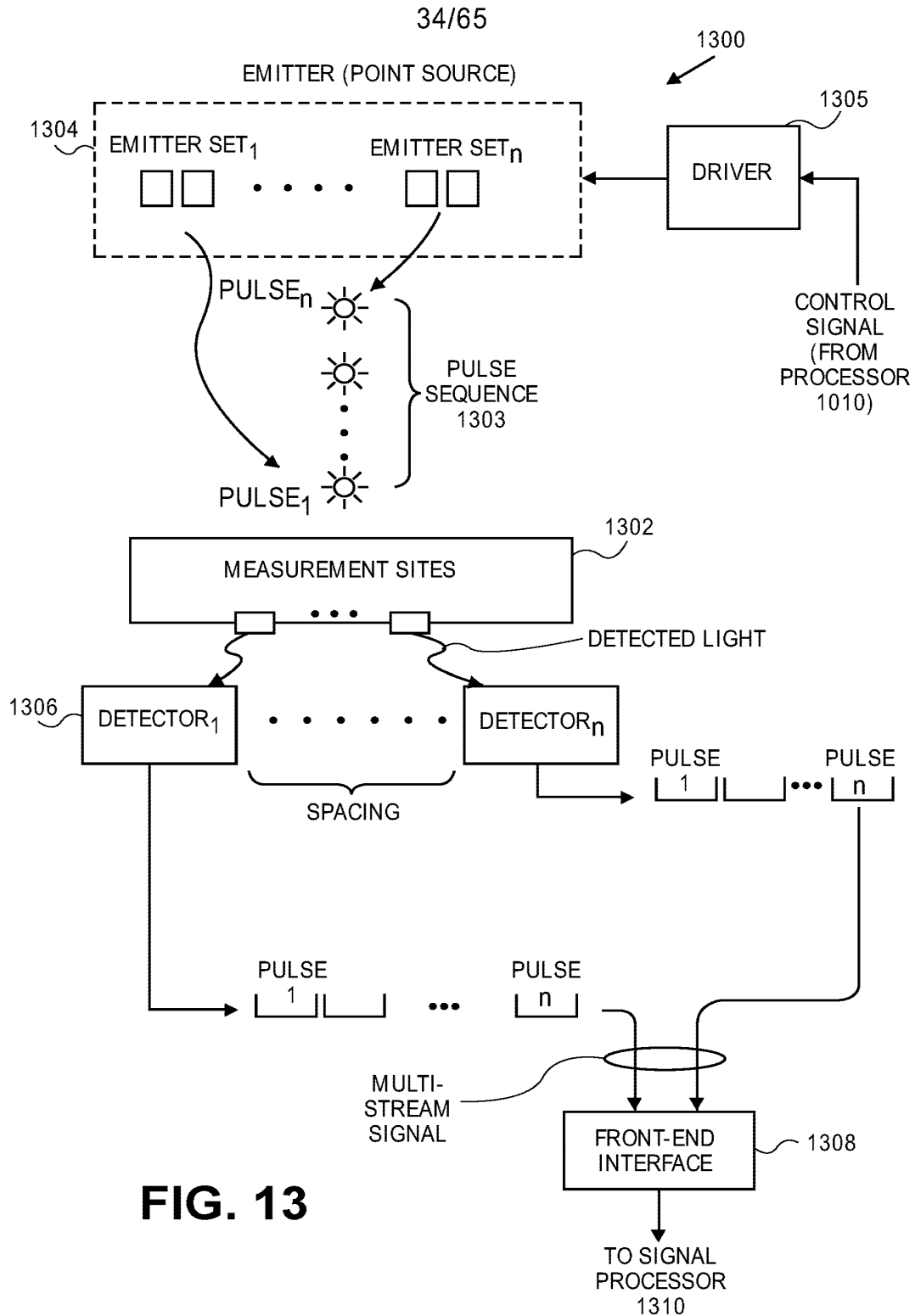


FIG. 12H



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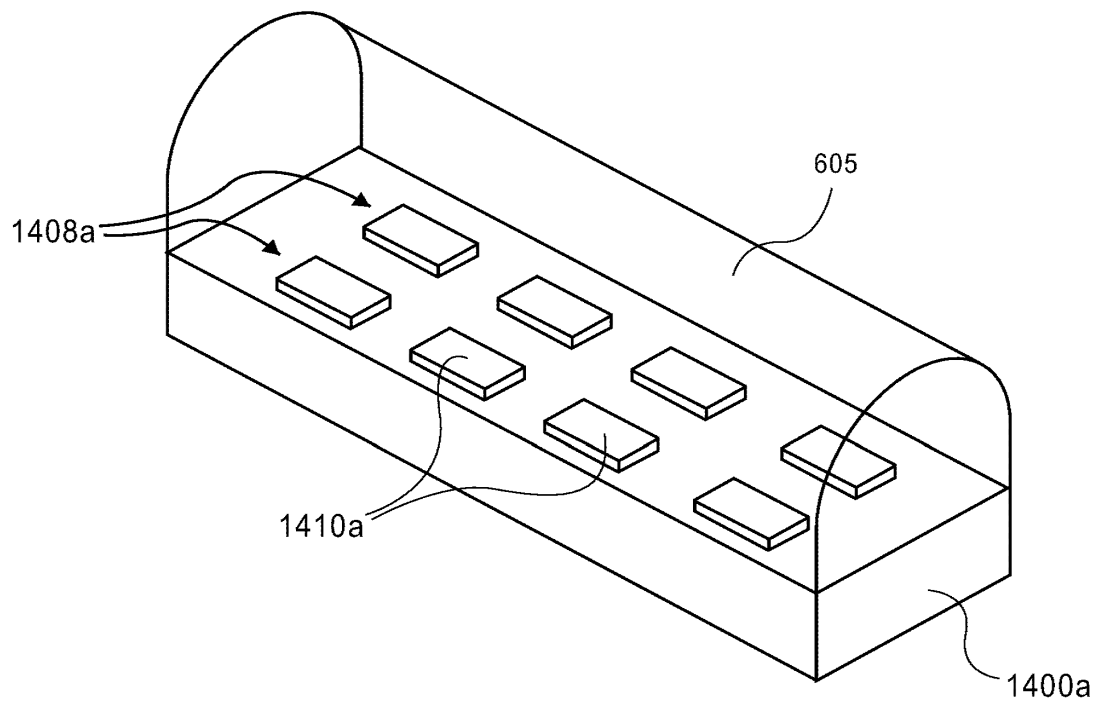


FIG. 14A

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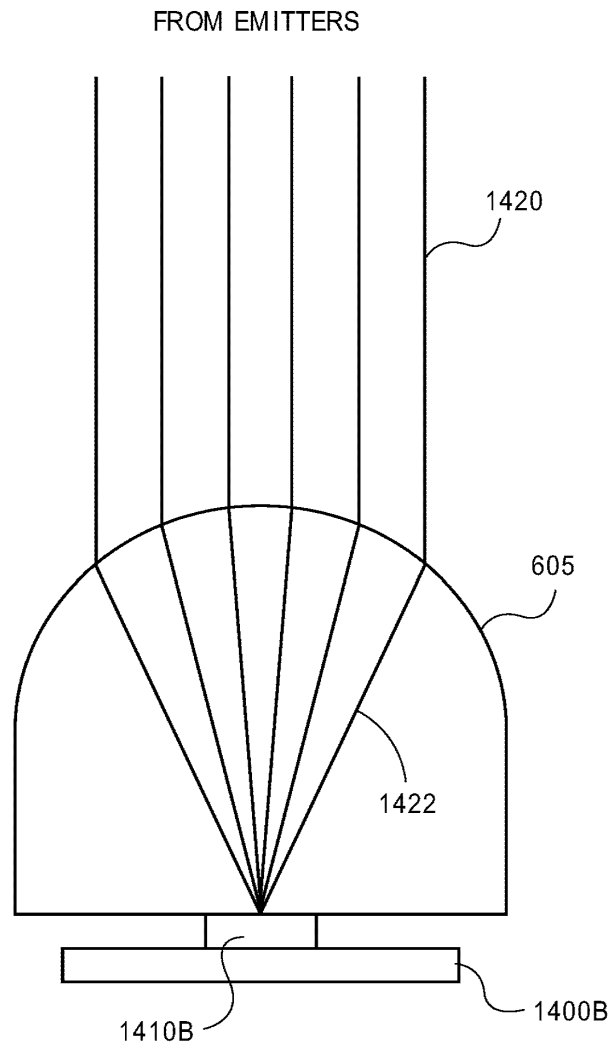


FIG. 14B

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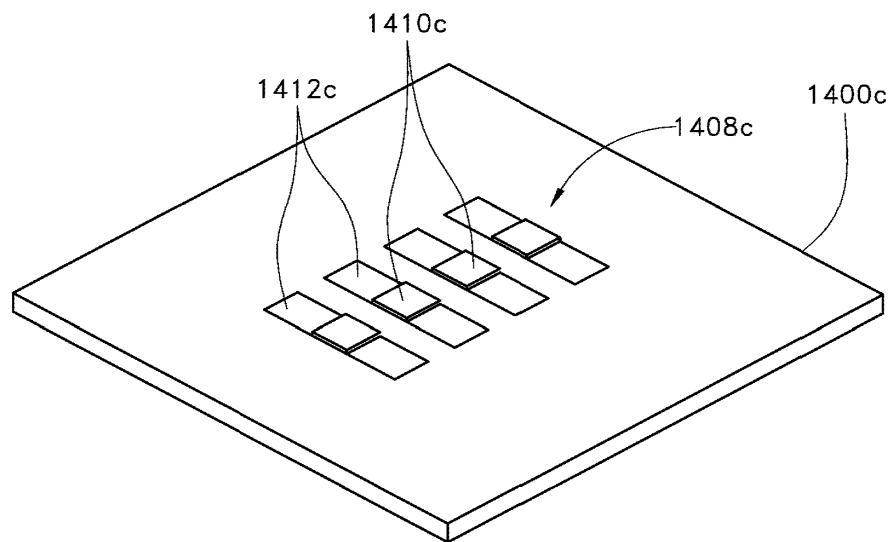


FIG. 14C

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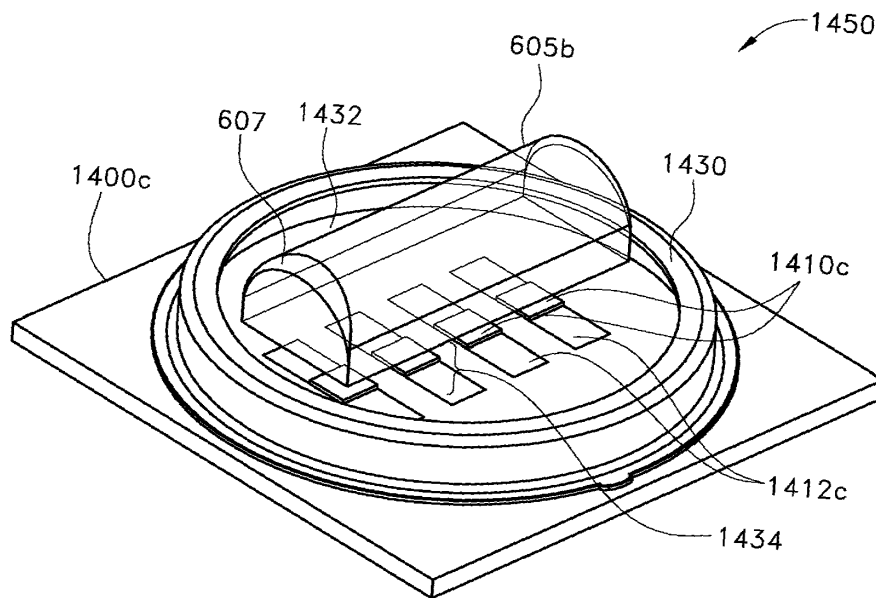


FIG. 14D

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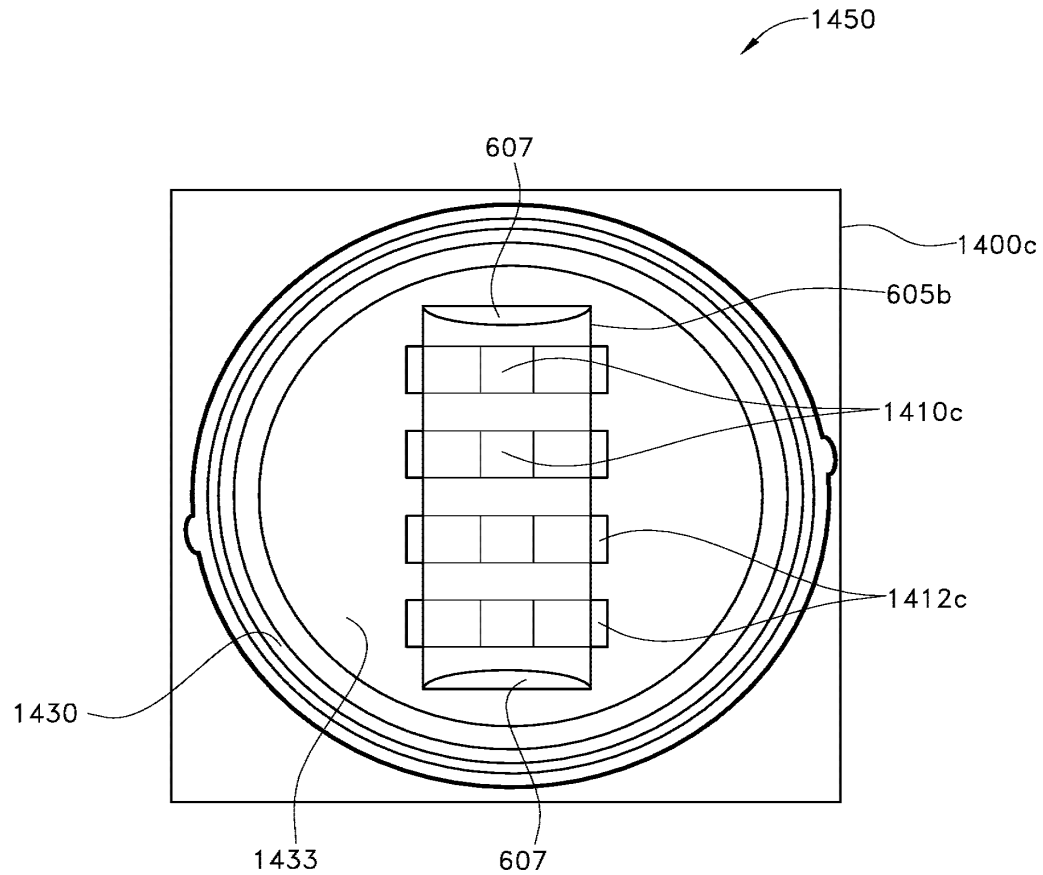


FIG. 14E

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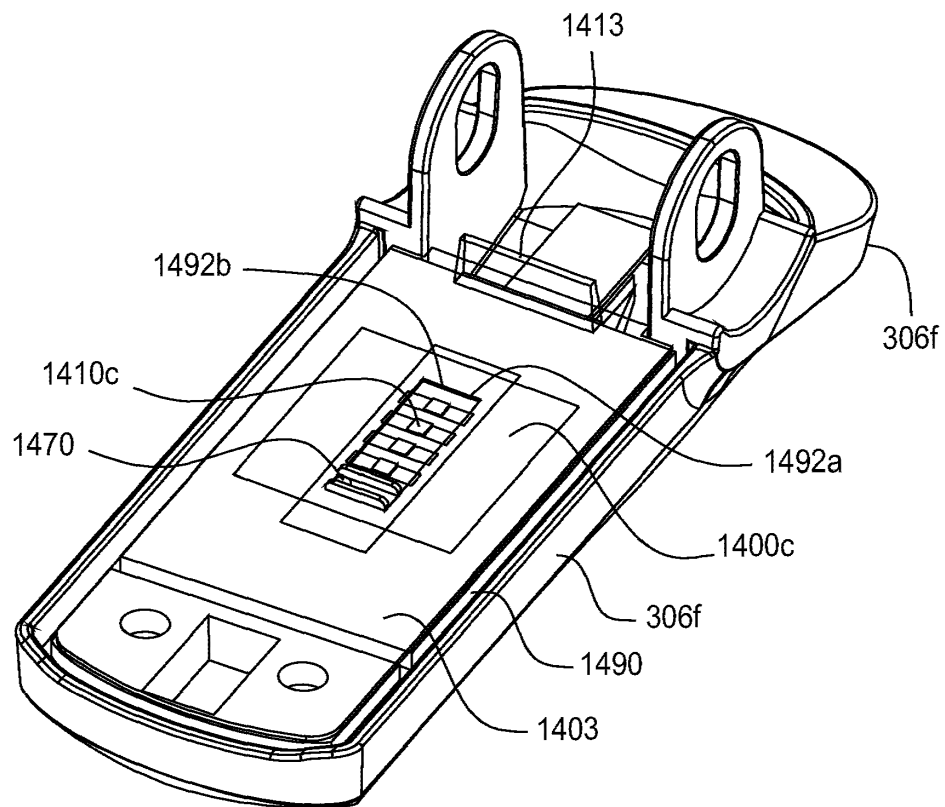


FIG. 14F

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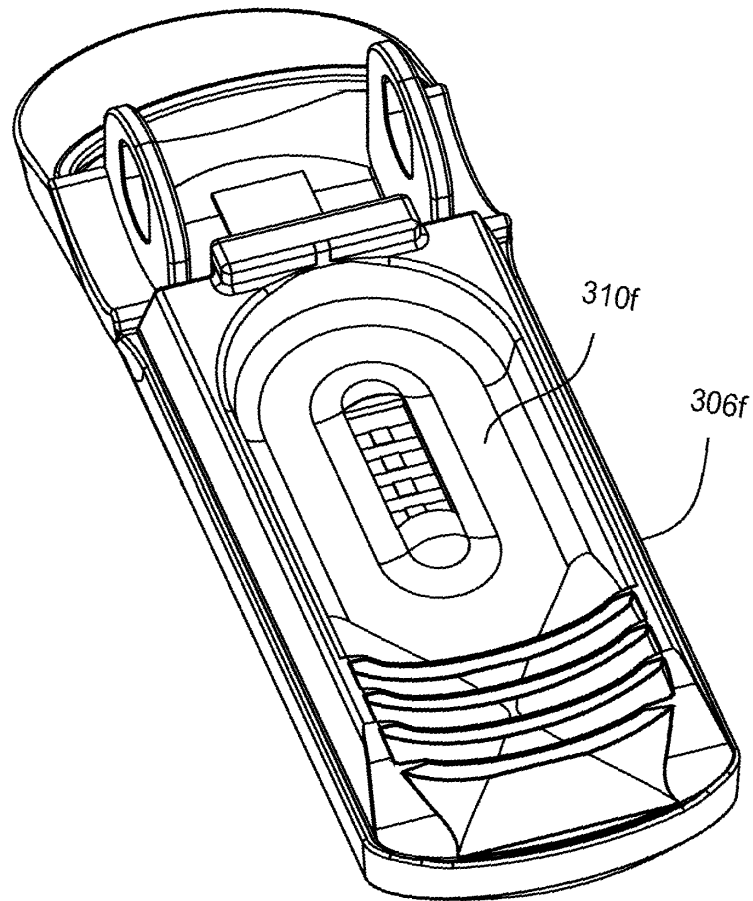


FIG. 14G

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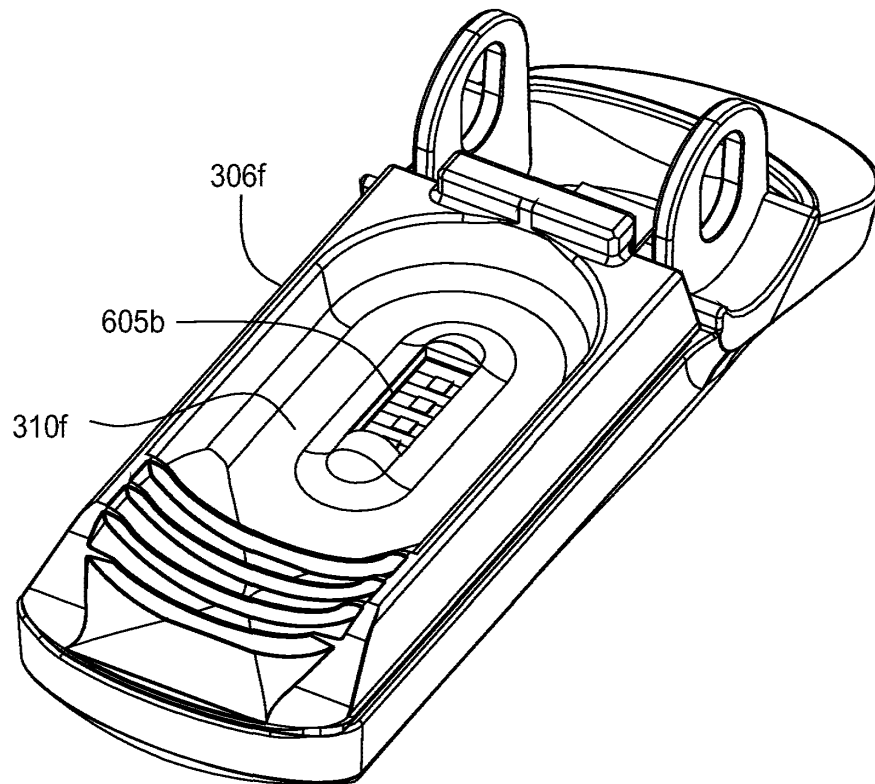


FIG. 14H

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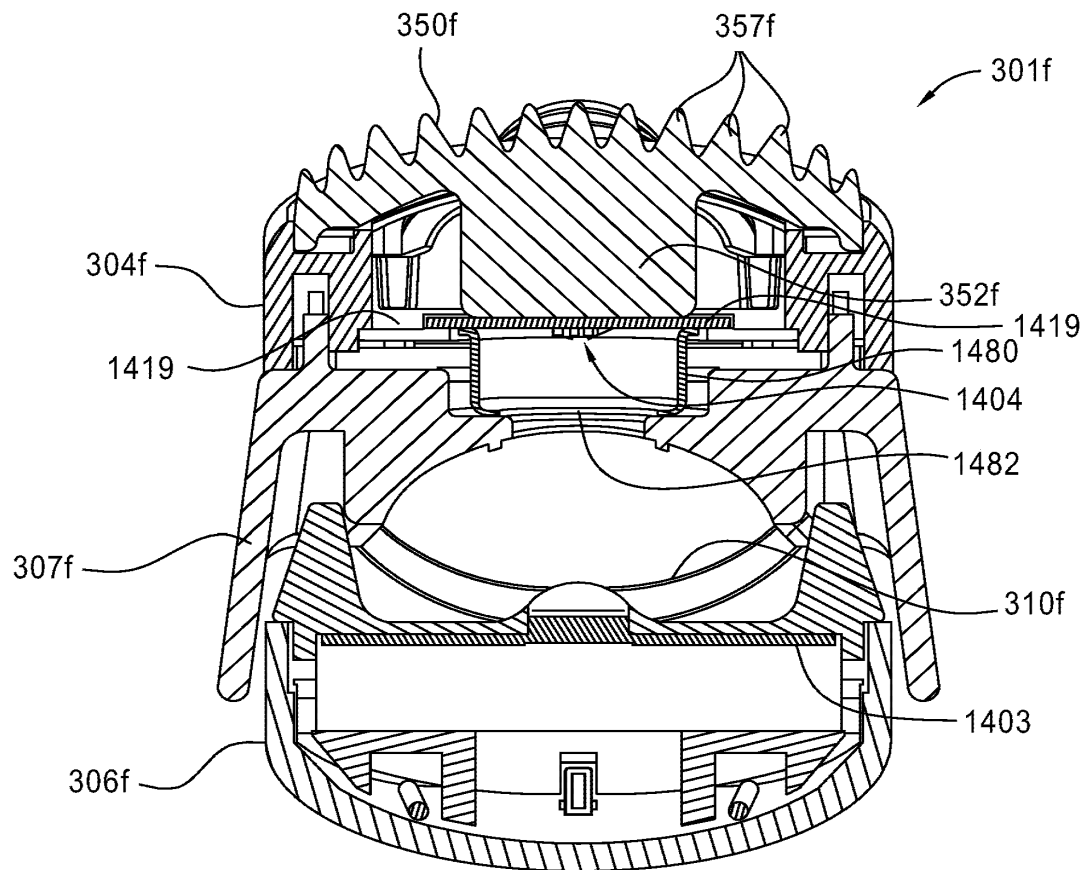


FIG. 14I

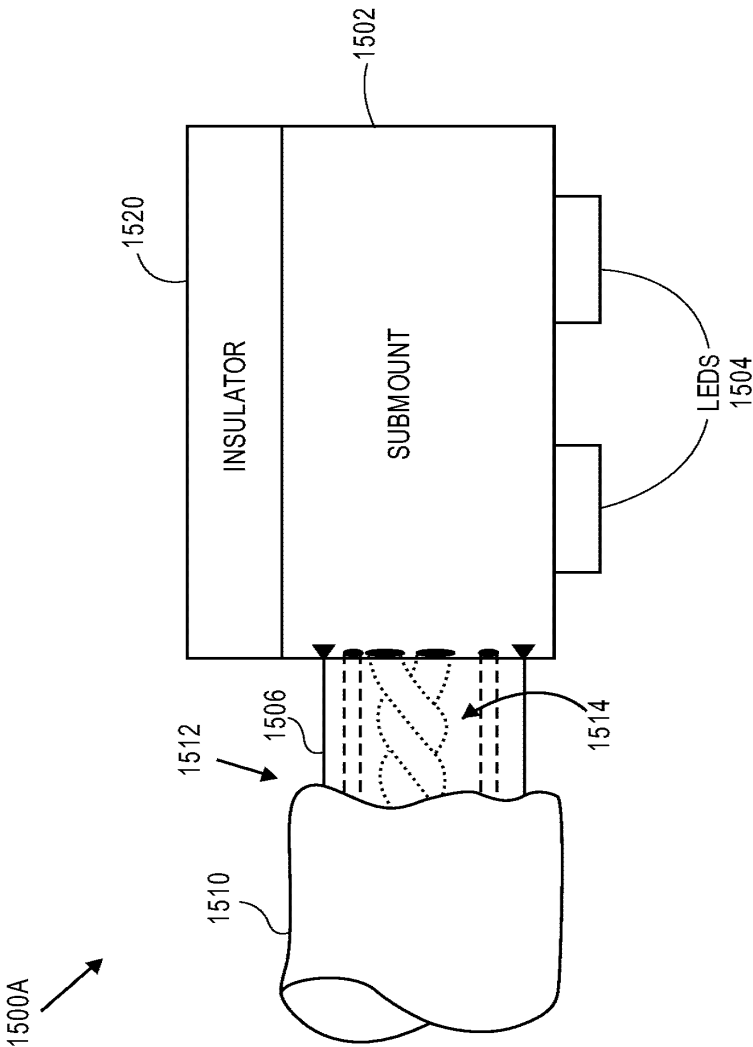


FIG. 15A

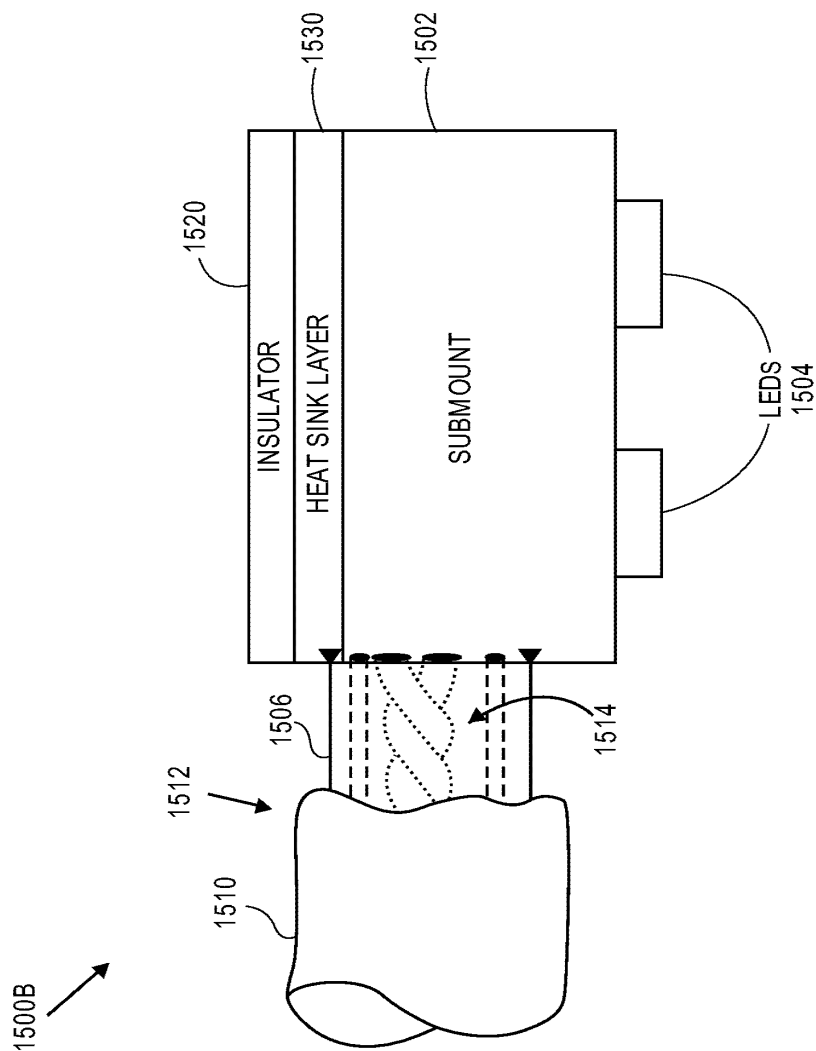


FIG. 15B

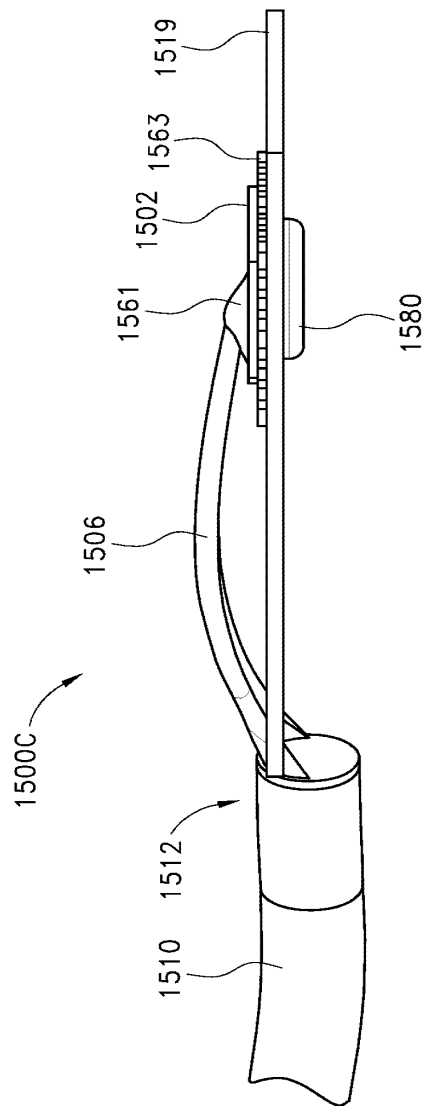
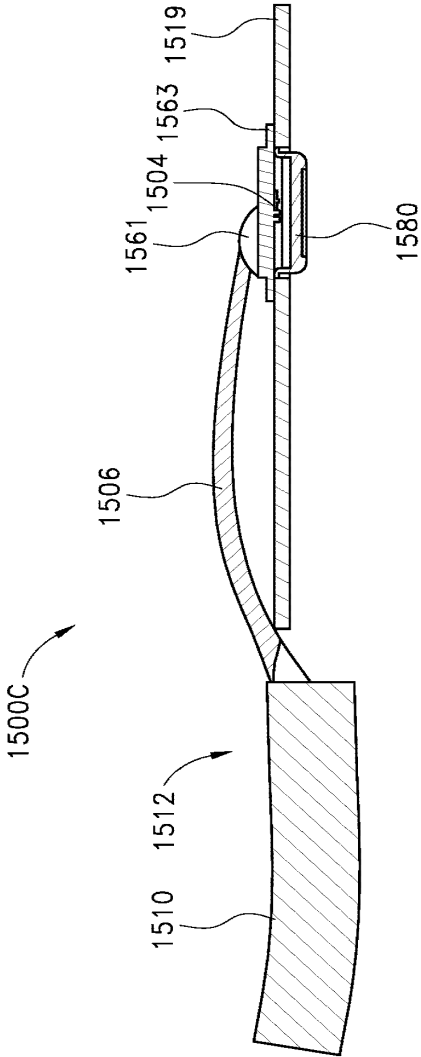


FIG. 15C



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FIG. 15D

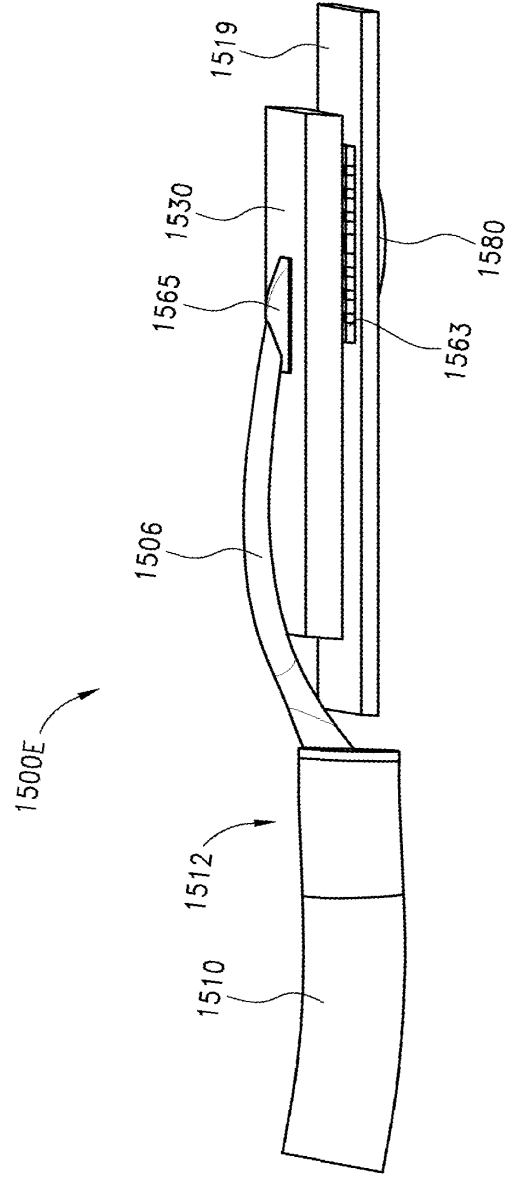


FIG. 15E

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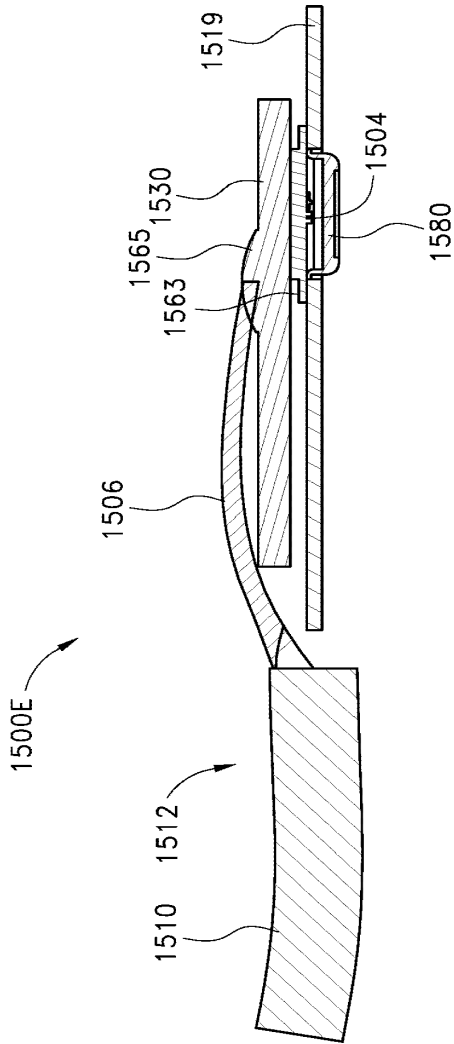


FIG. 15F

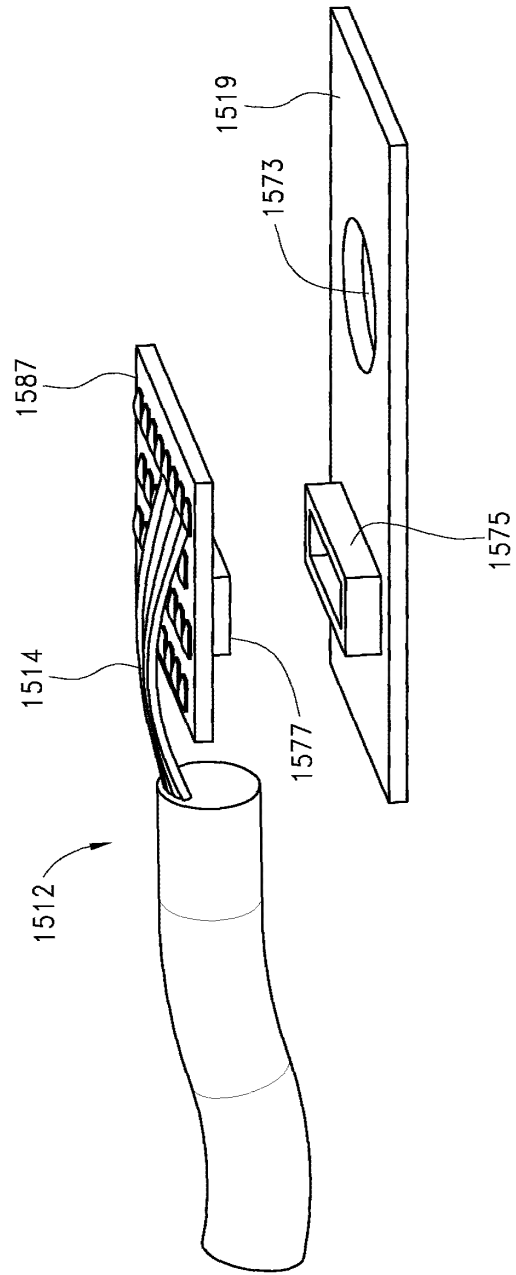


FIG. 15G

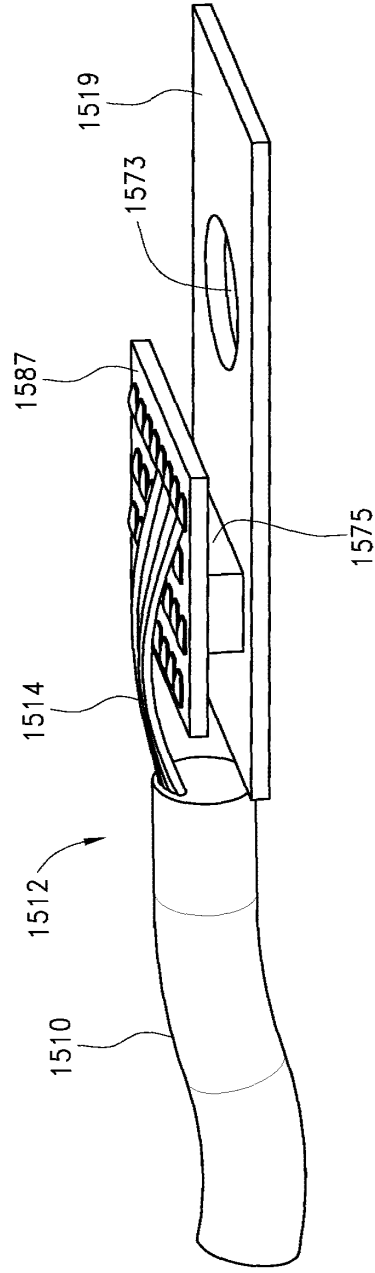


FIG. 15H

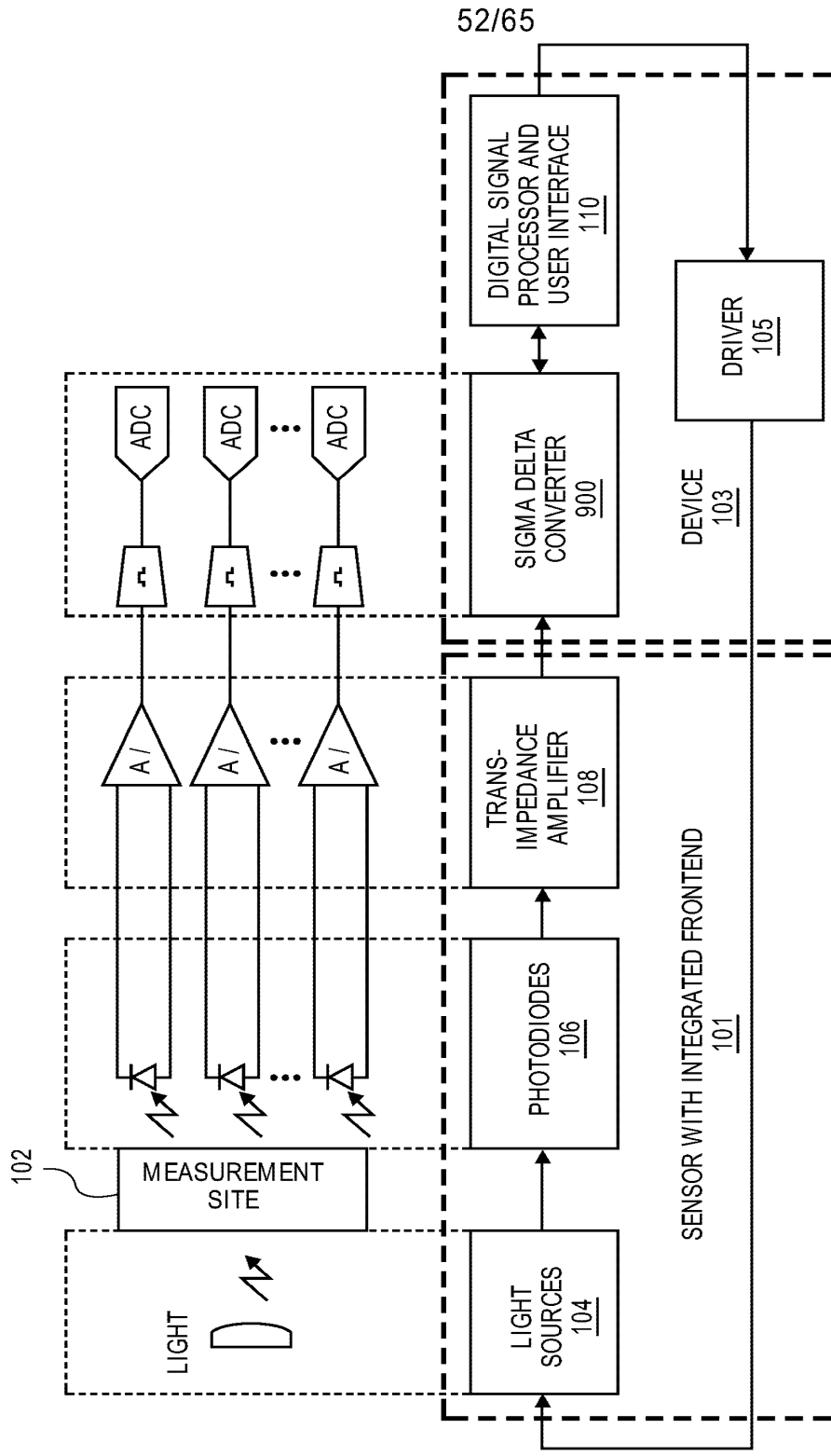
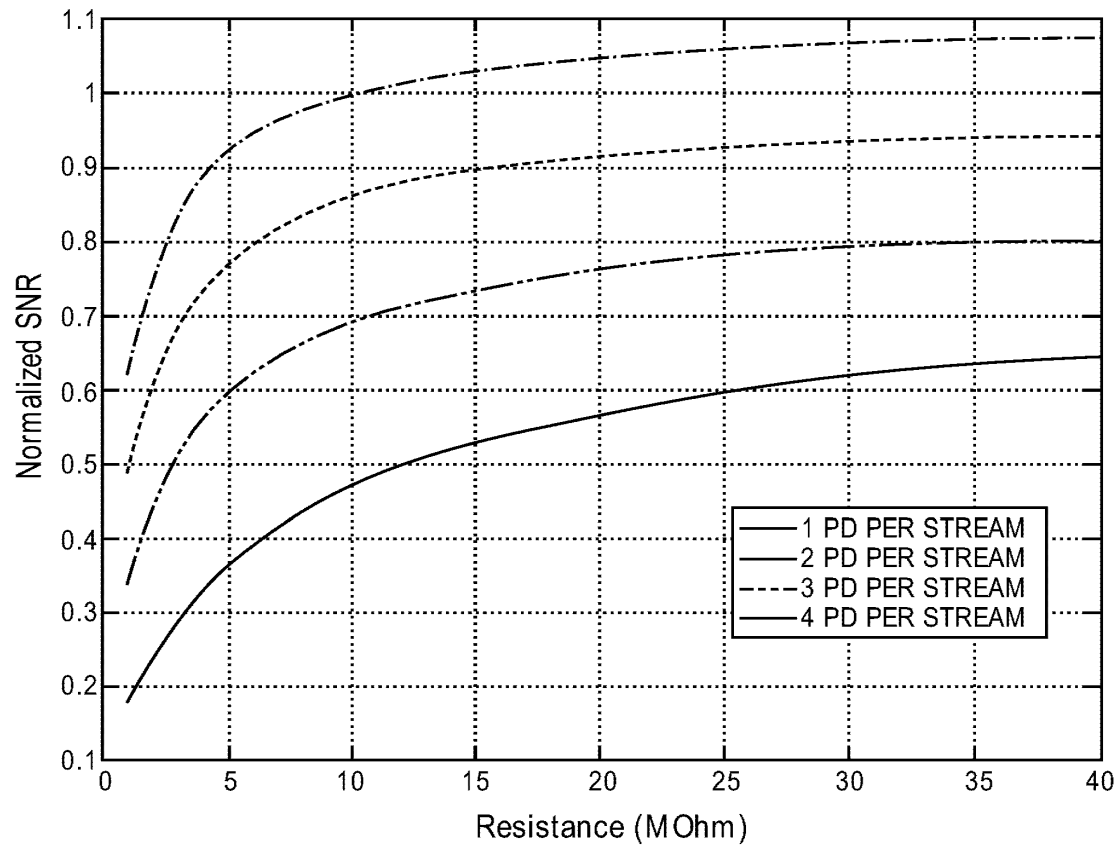
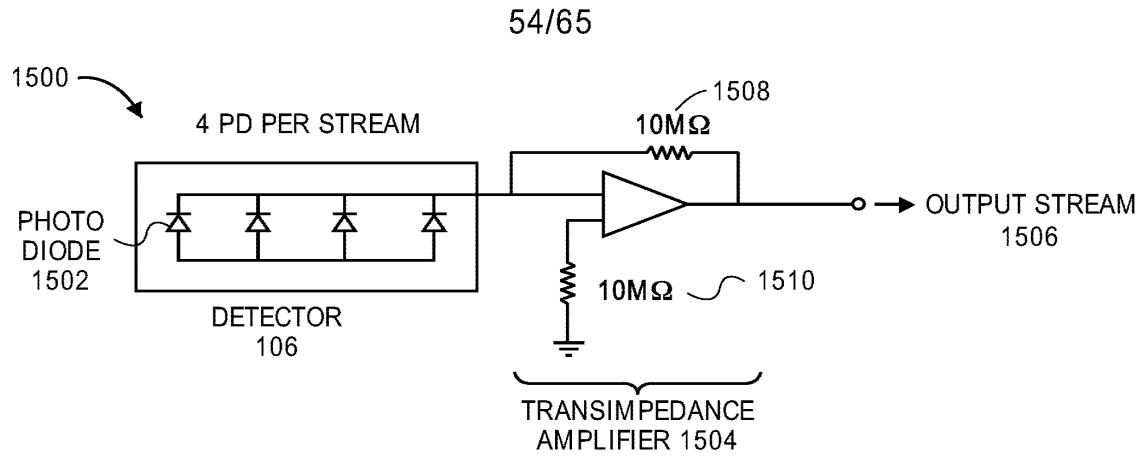


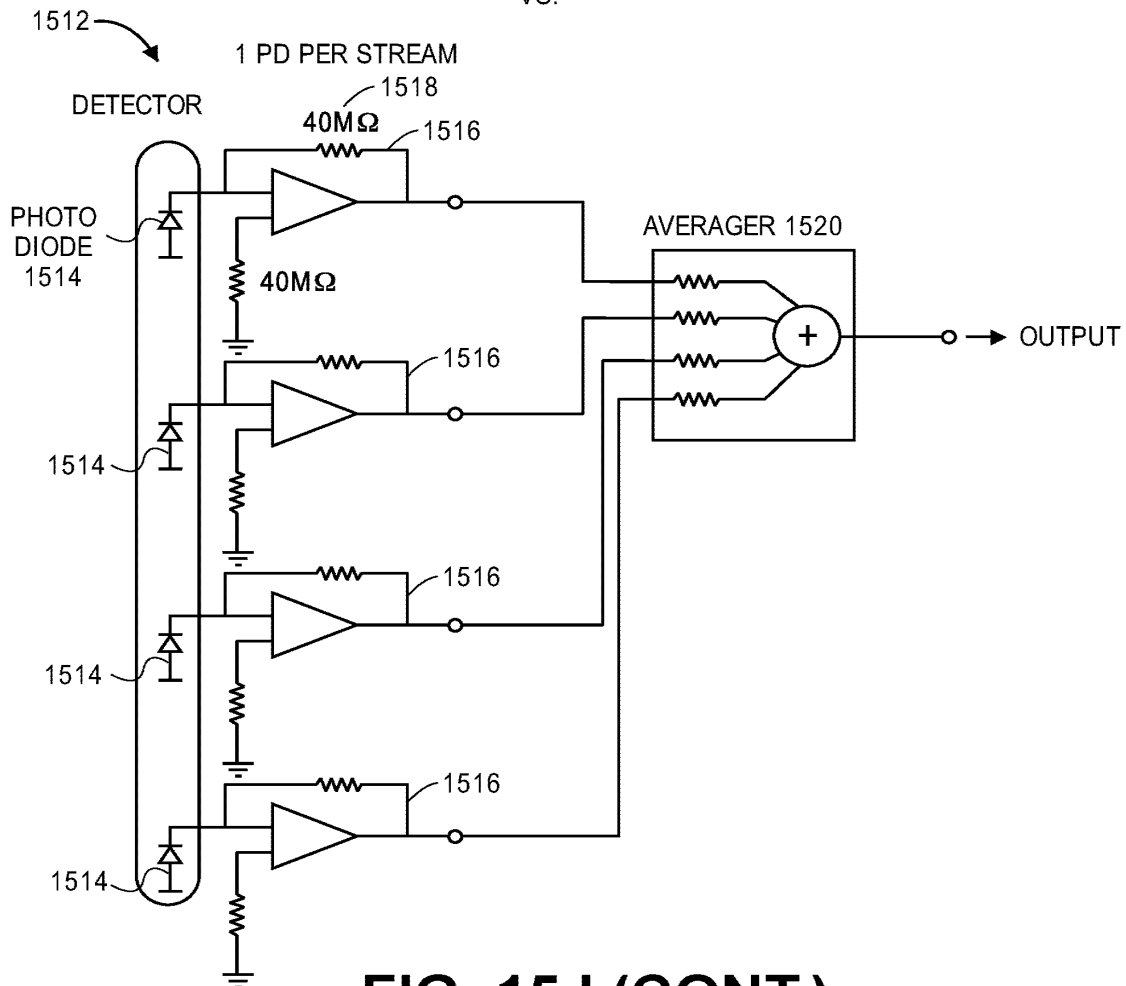
FIG. 151

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**FIG. 15J**



VS.

**FIG. 15J (CONT.)**

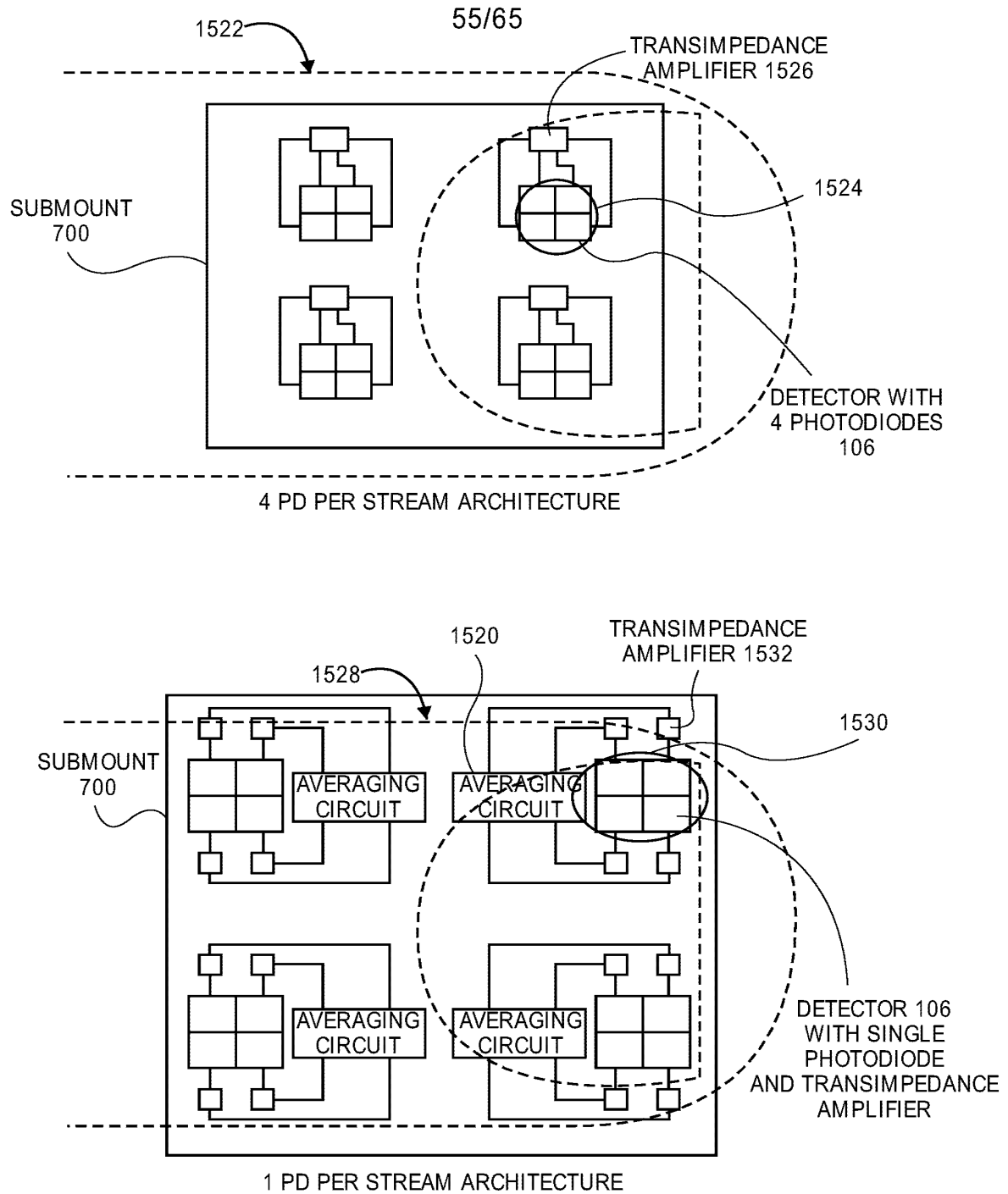
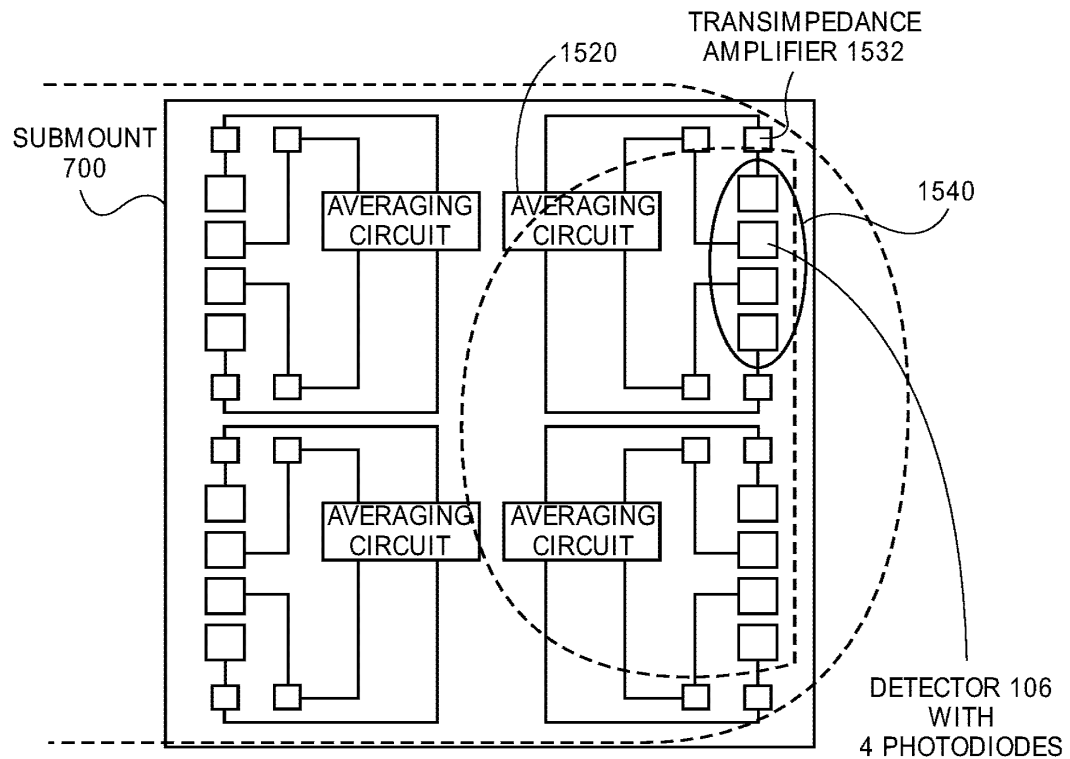
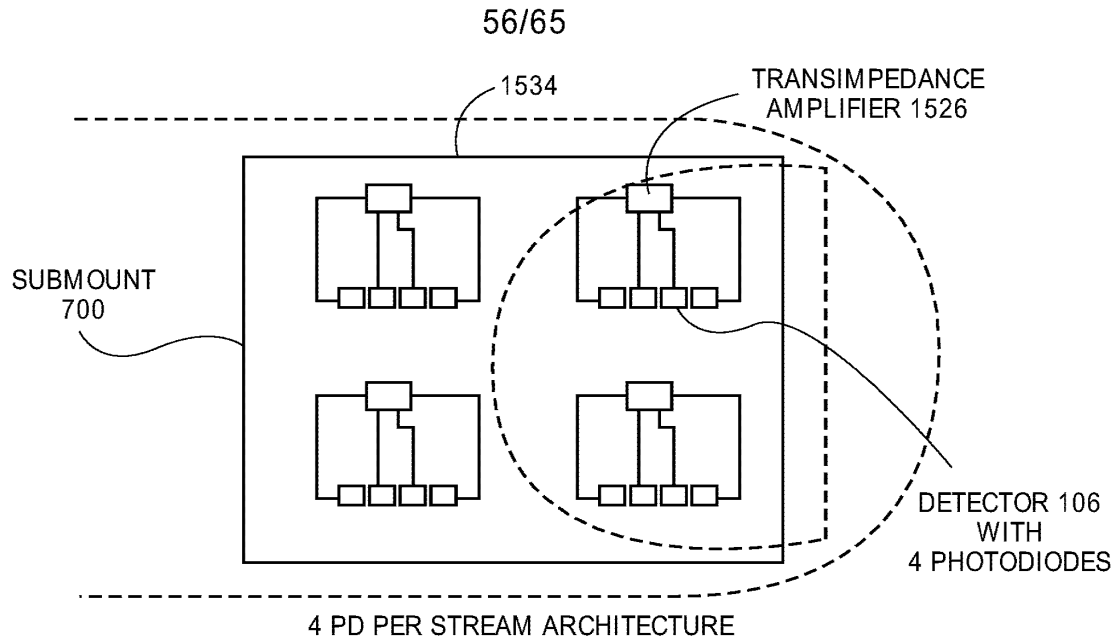


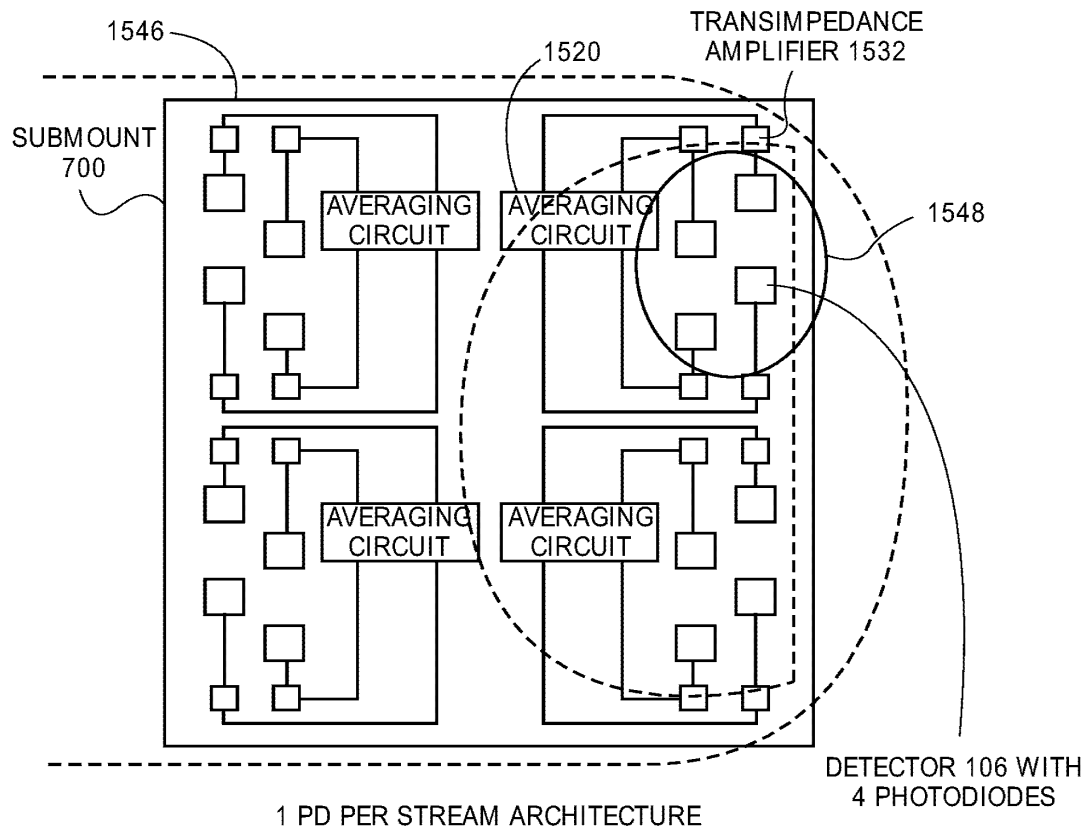
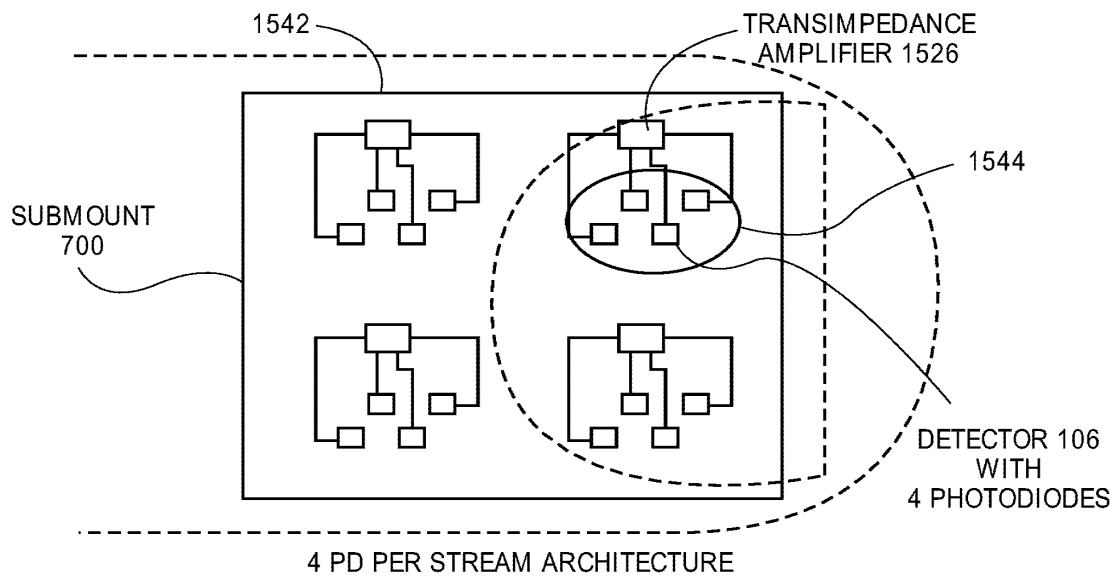
FIG. 15K



1 PD PER STREAM ARCHITECTURE

FIG. 15K (CONT.)

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**FIG. 15K (CONT.)**

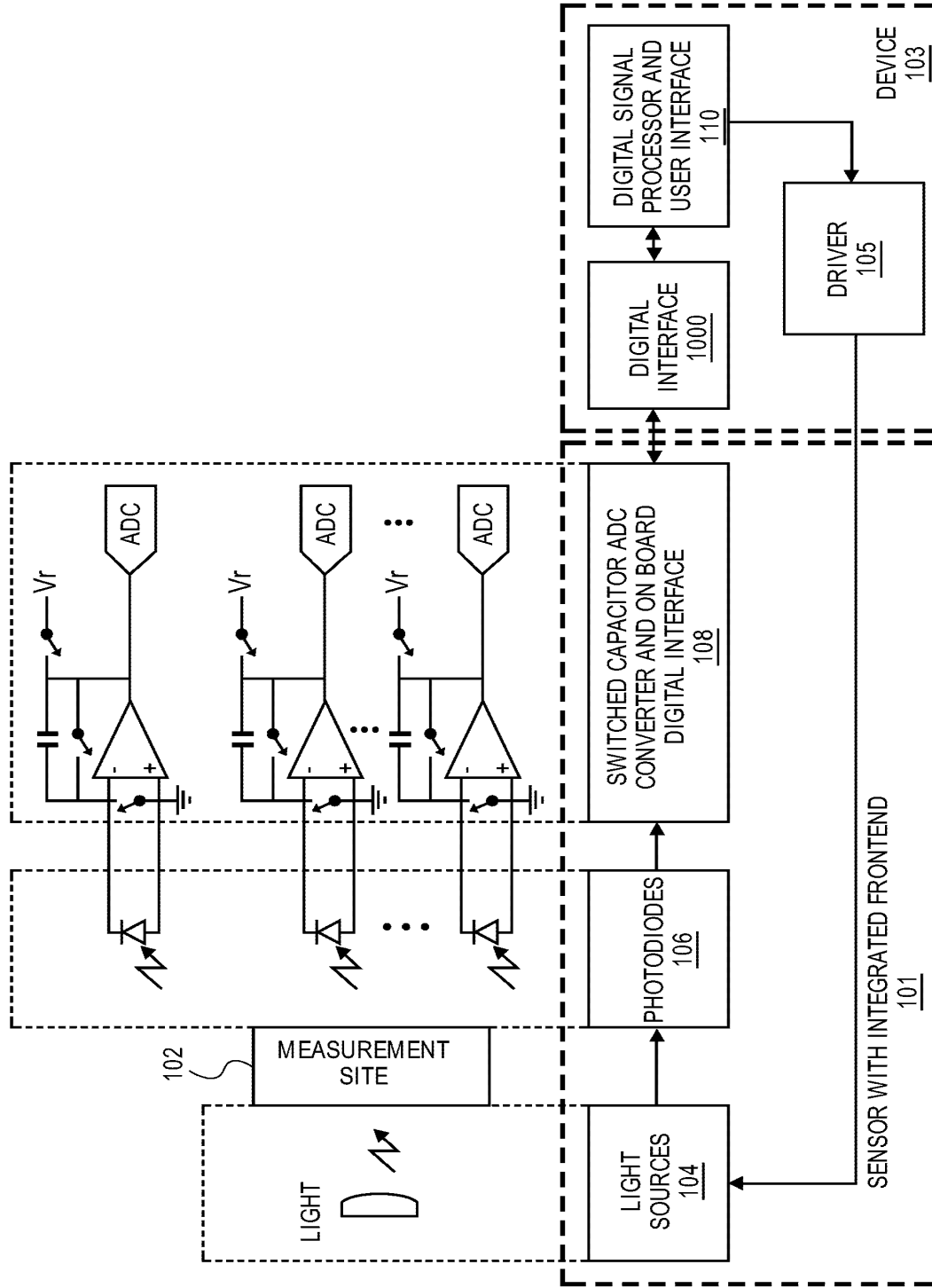
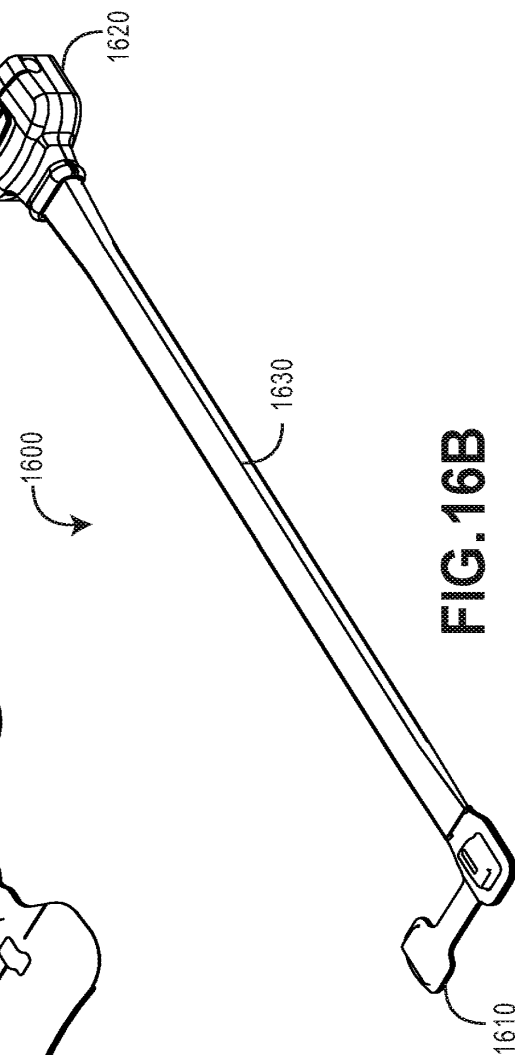
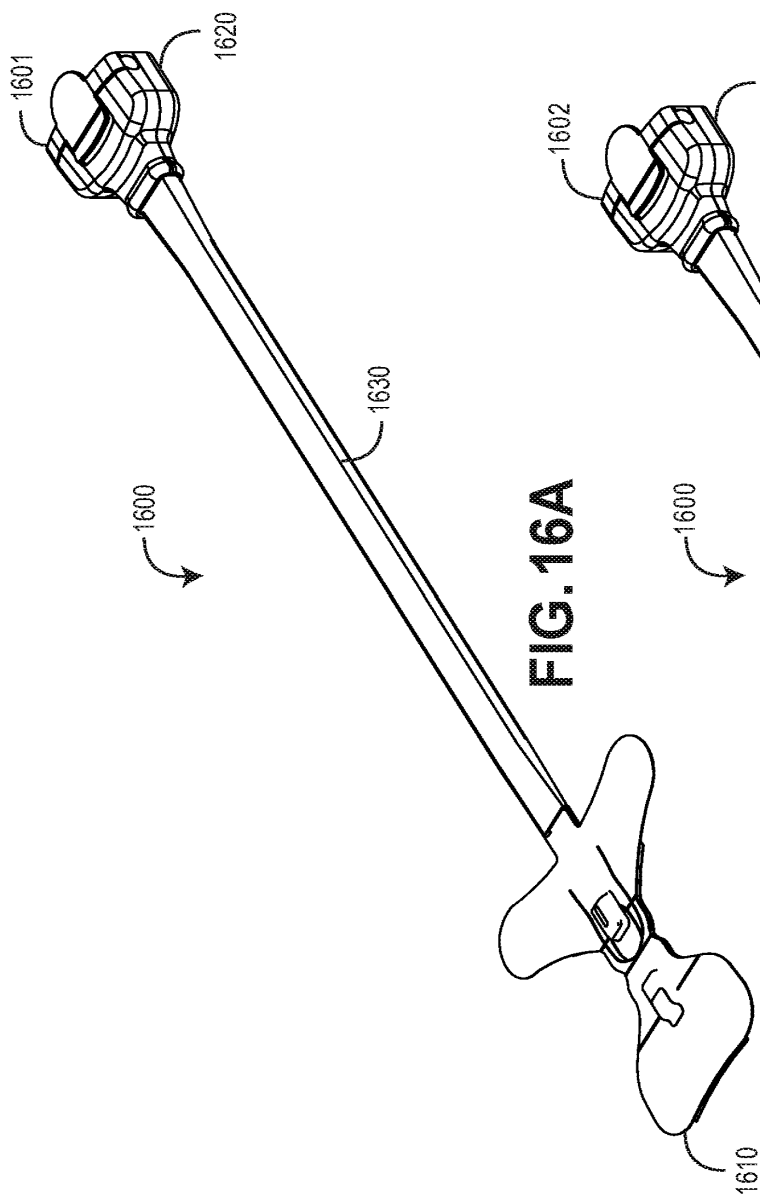


FIG. 15L

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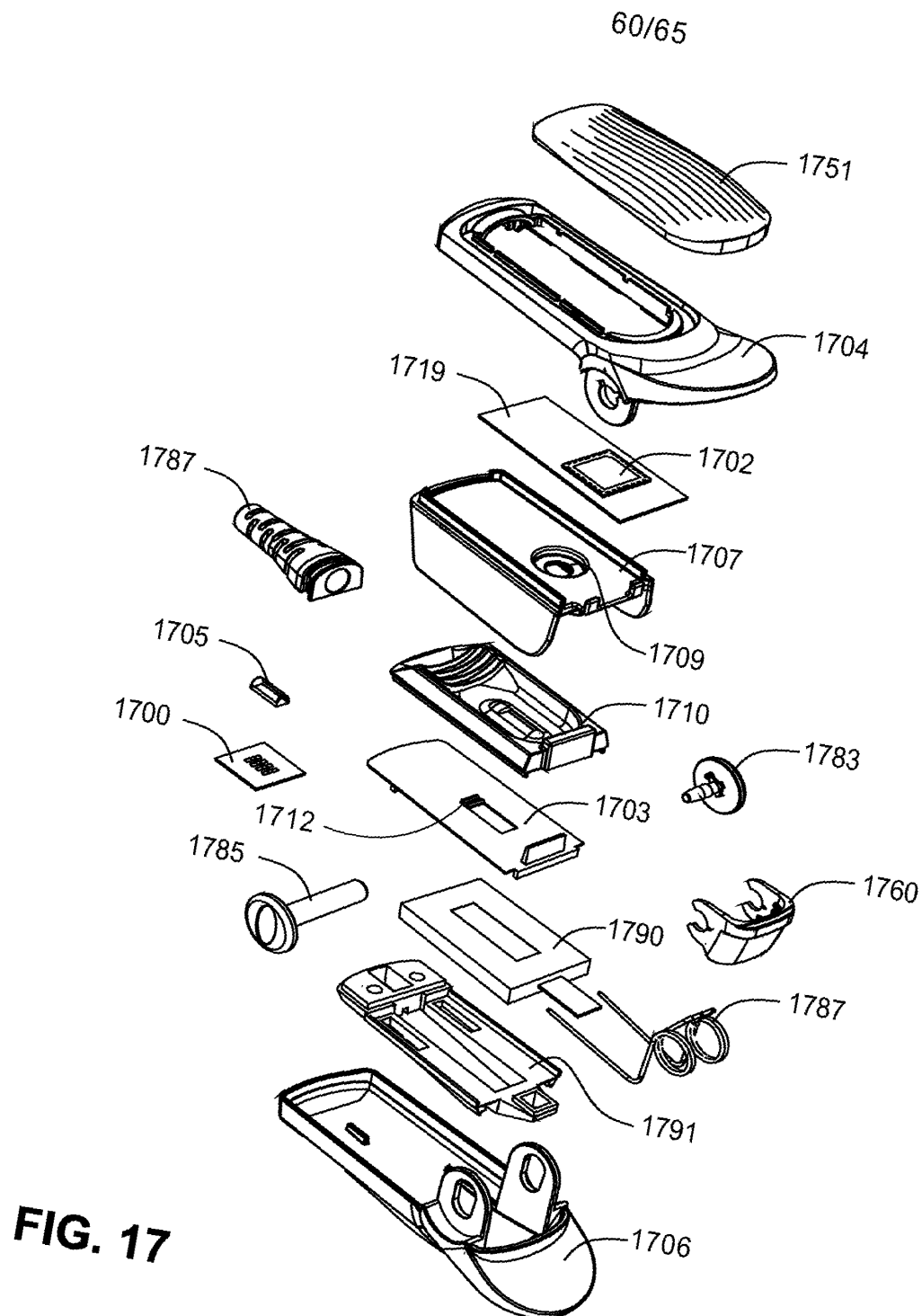
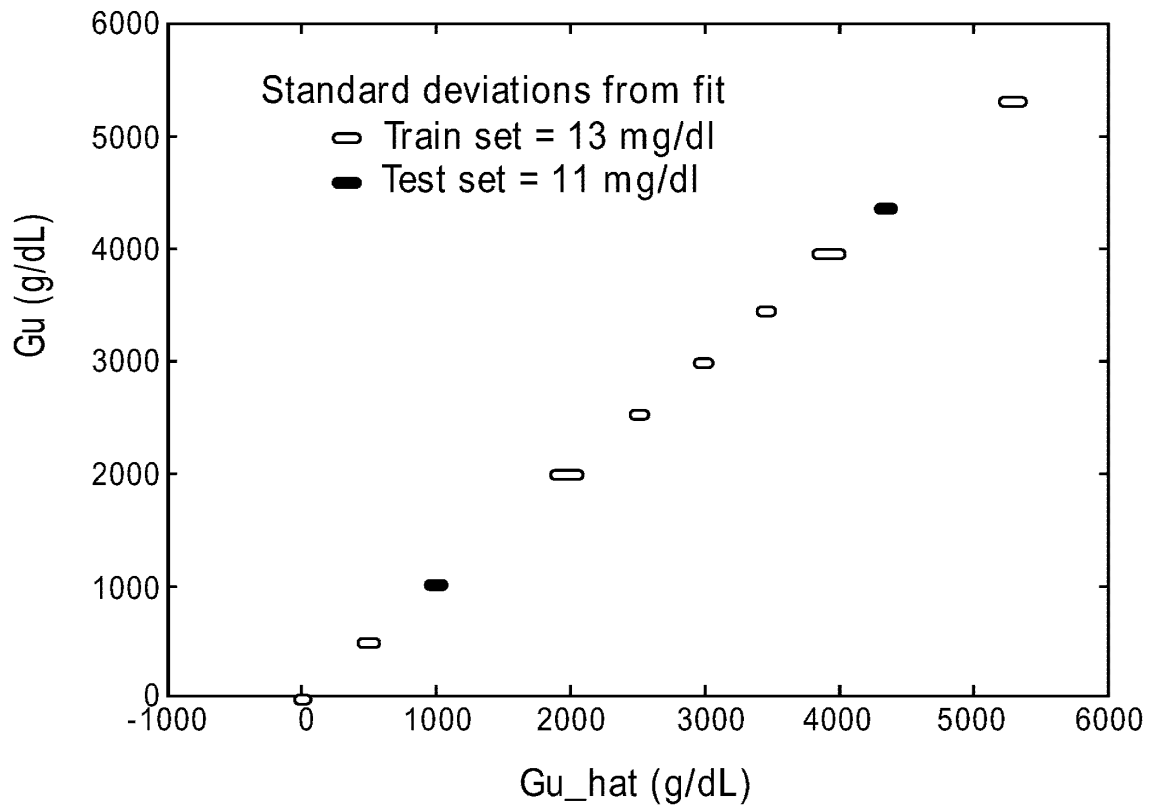
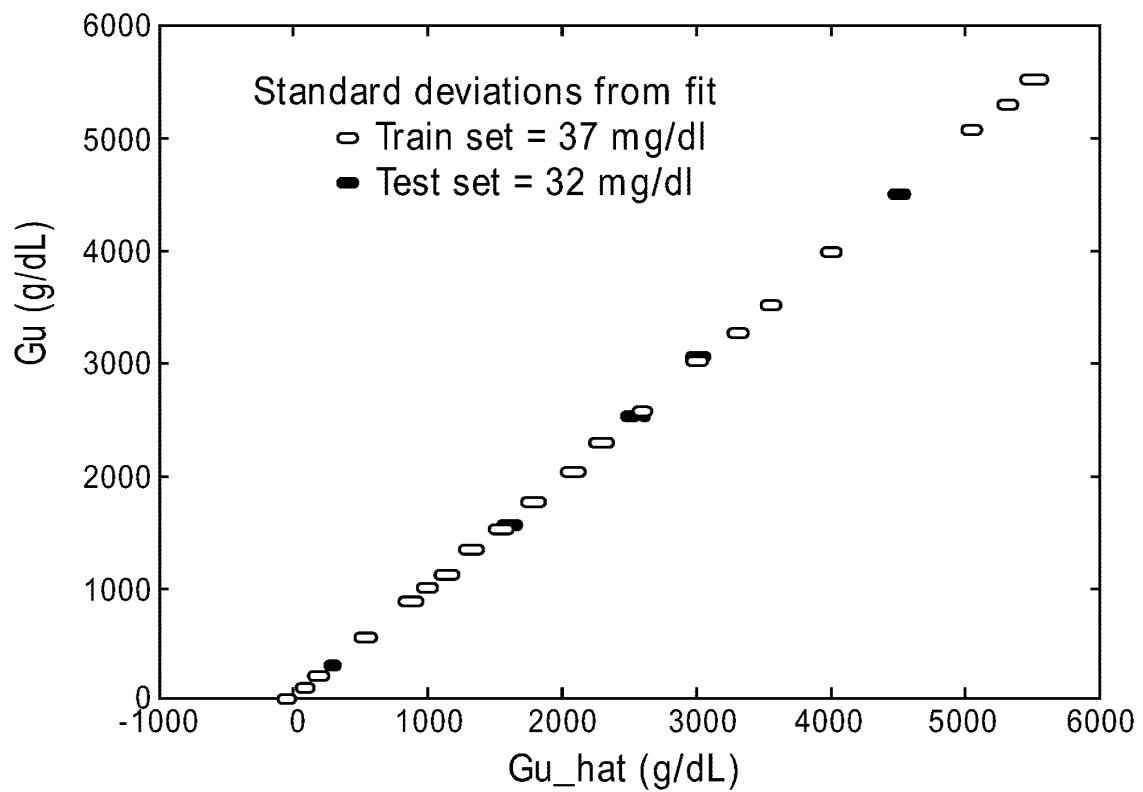


FIG. 17

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**FIG. 18**

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**FIG. 19**

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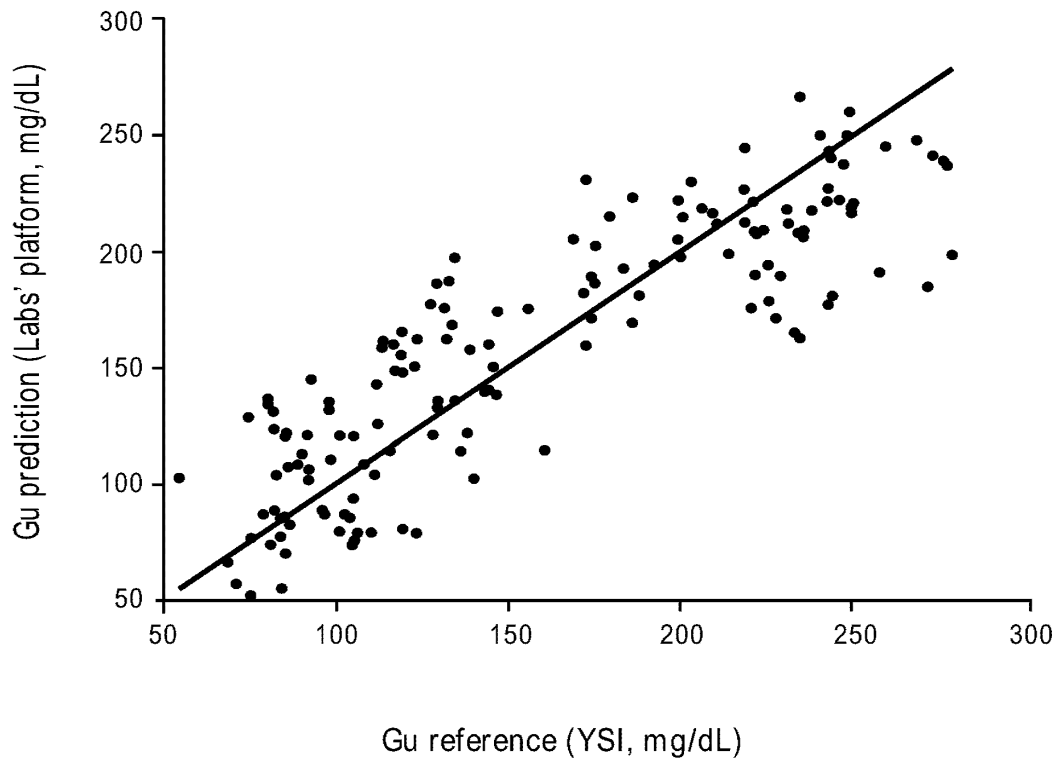
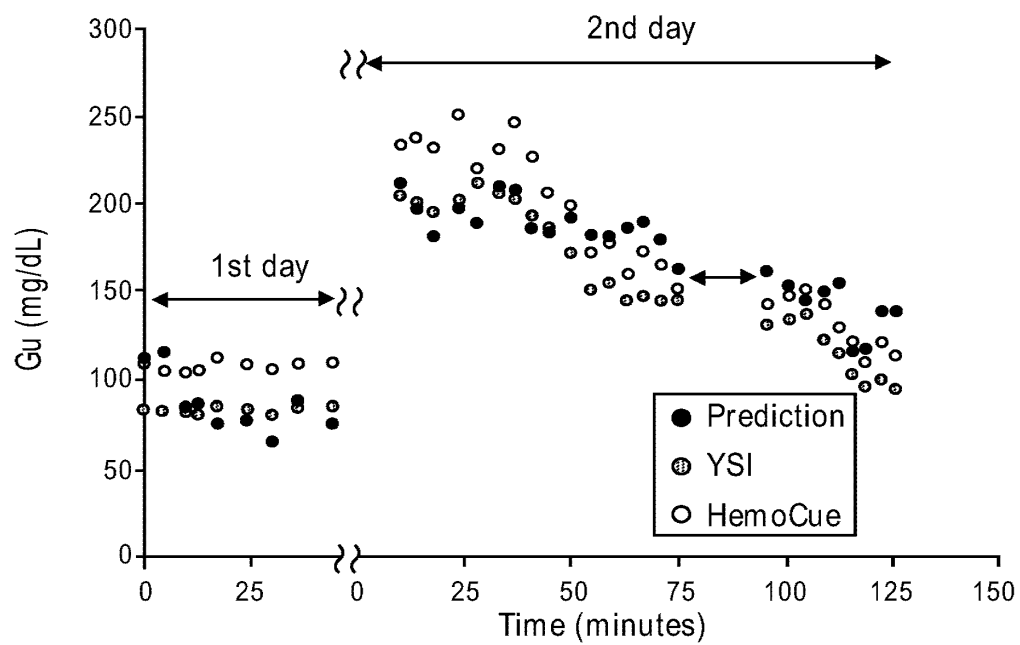


FIG. 20

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**FIG. 21**

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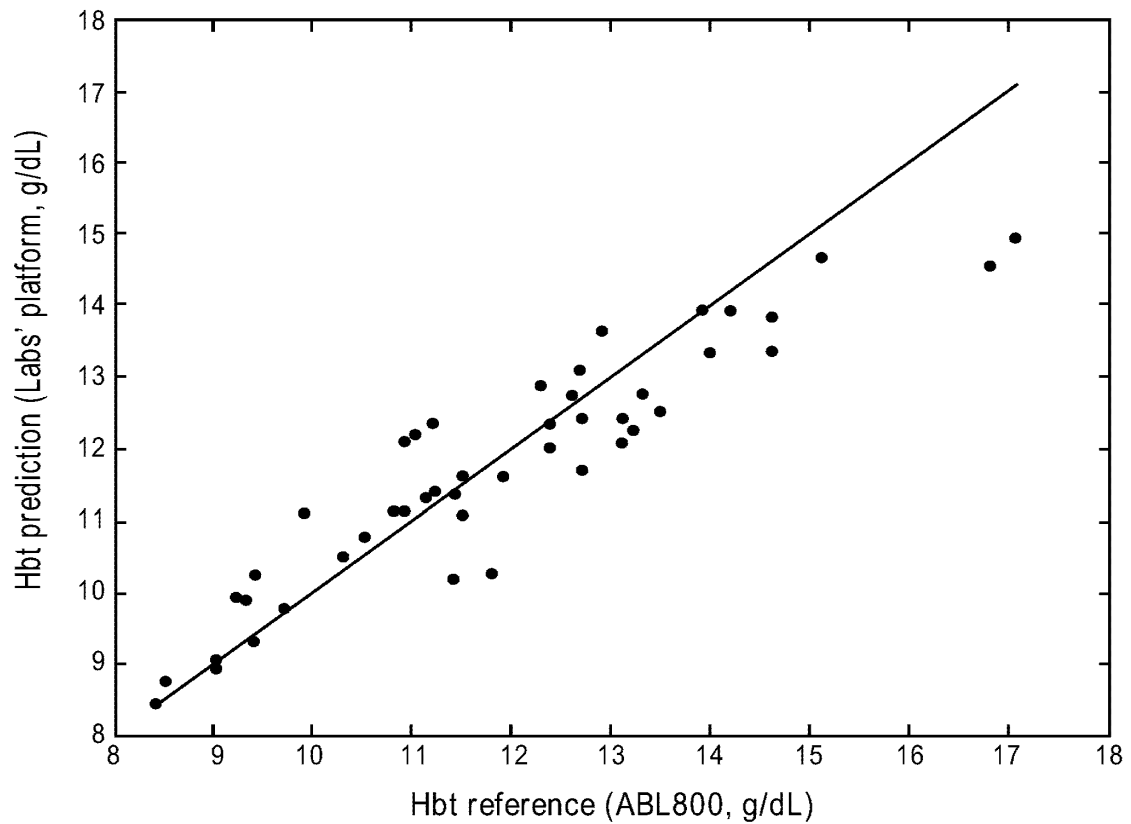


FIG. 22

APPX60136-60153
ENTIRELY REDACTED

APPX60184-60212
ENTIRELY REDACTED

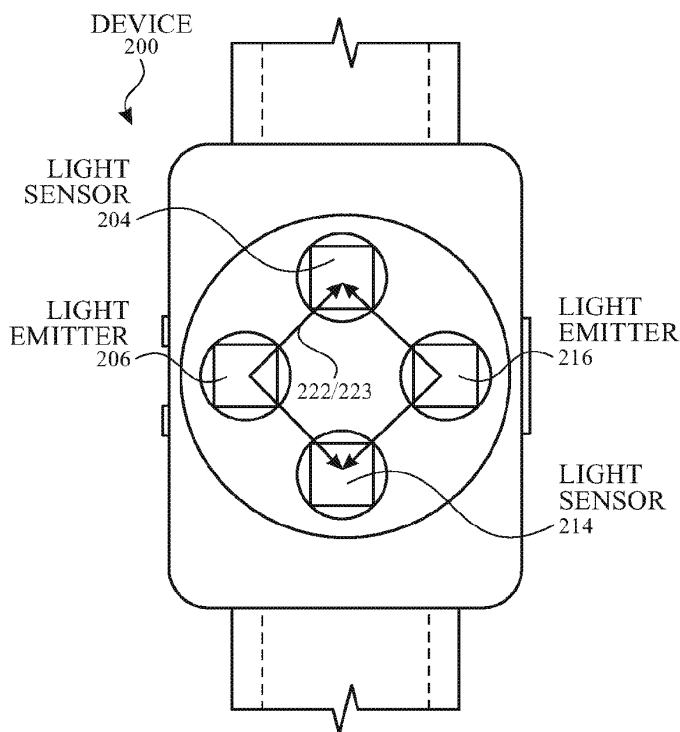
APPX60425-60434
ENTIRELY REDACTED

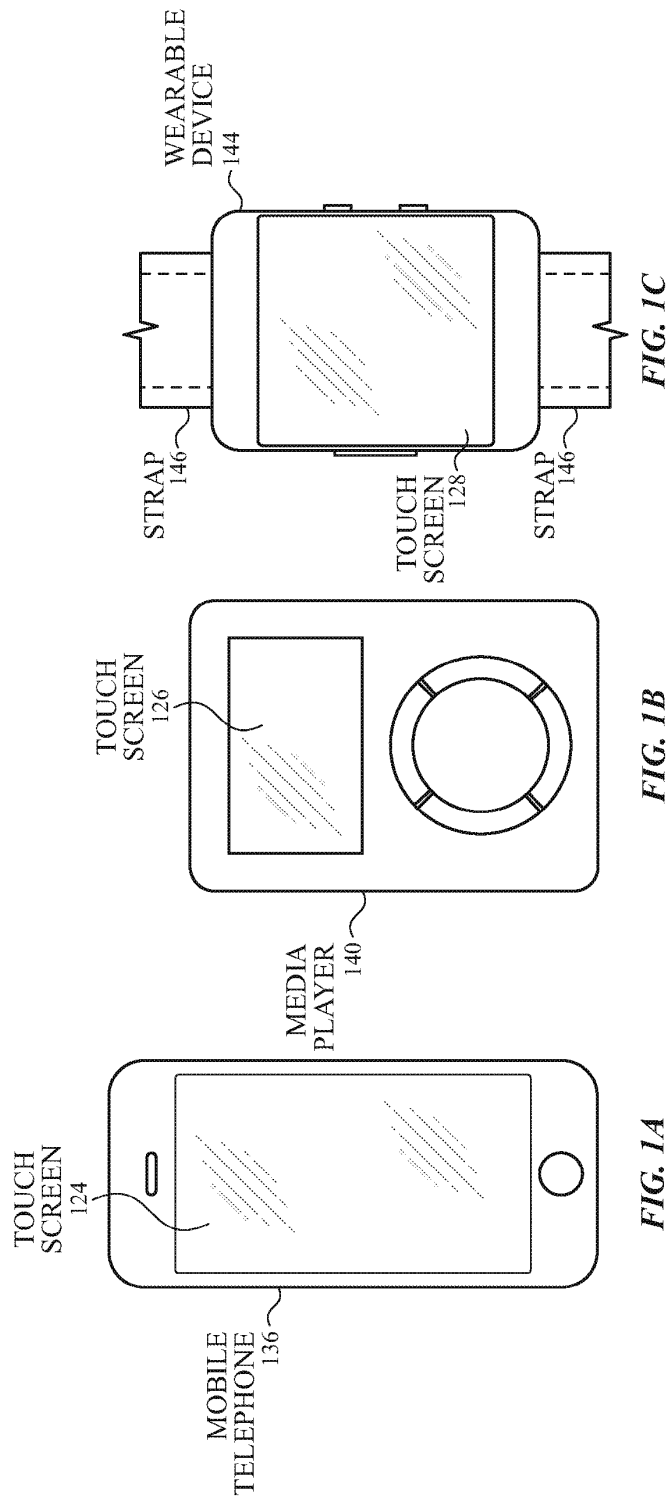


US 20170325744A1

(19) **United States**(12) **Patent Application Publication**
ALLEC et al.(10) **Pub. No.: US 2017/0325744 A1**
(43) **Pub. Date: Nov. 16, 2017**(54) **SYSTEMS AND METHODS FOR
INCREASING LOCALIZED PRESSURE TO
IMPROVE PPG MOTION PERFORMANCE**(52) **U.S. Cl.**
CPC *A61B 5/6843* (2013.01); *A61B 5/681*
(2013.01); *A61B 5/6898* (2013.01); *A61B*
5/02427 (2013.01); *A61B 2562/146* (2013.01);
A61B 2562/0238 (2013.01); *A61B 2562/0219*
(2013.01); *A61B 2562/185* (2013.01); *G02B*
3/08 (2013.01); *G02B 27/30* (2013.01); *A61B*
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Tobias J. HARRISON-NOONAN, San
Francisco, CA (US); **Ueyn L. BLOCK**,
Menlo Park, CA (US); **Vivek**
VENUGOPAL, San Jose, CA (US)(21) Appl. No.: **15/592,020**(22) Filed: **May 10, 2017****Related U.S. Application Data**(60) Provisional application No. 62/397,791, filed on Sep.
21, 2016, provisional application No. 62/334,363,
filed on May 10, 2016.**Publication Classification**(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/024 (2006.01)
A61B 5/00 (2006.01)
A61B 5/00 (2006.01)(57) **ABSTRACT**

The relates to a back surface of the device including one or more protrusions configured to create the localized pressure. In some examples, the protrusion(s) can be located between the optical components and one or more edges of the back plate. In some examples, the protrusion(s) can include a surface that can be raised relative to the back plate of the device. In some examples, one or more protrusions can include one or more recessed regions. In some examples, the cover structure disposed over each of the openings may itself be a protrusion that can apply local regions of higher pressure. The protrusion(s) can be capable of applying localized pressure to multiple spatially separated regions of the skin. Additionally or alternatively, the protrusion(s) can be capable of applying different amounts of localized pressure. Examples of the disclosure can include the Fresnel lens(es) and/or optical isolation optically coupled to the protrusion.





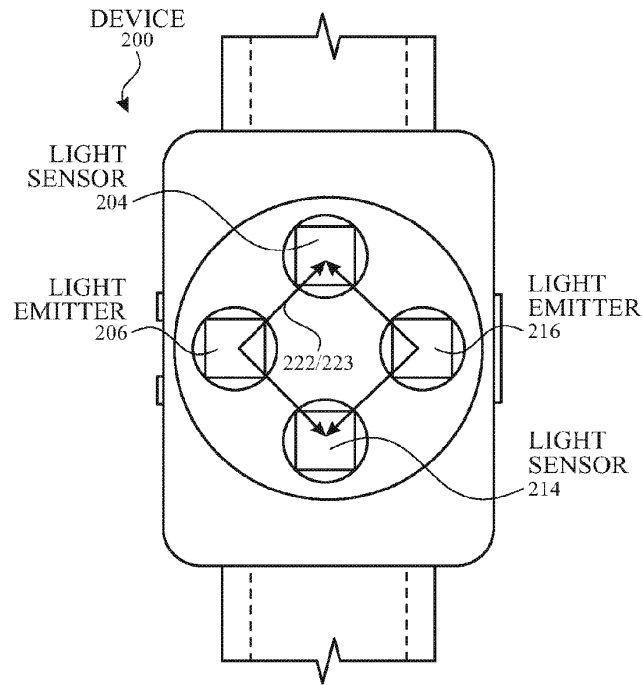


FIG. 2A

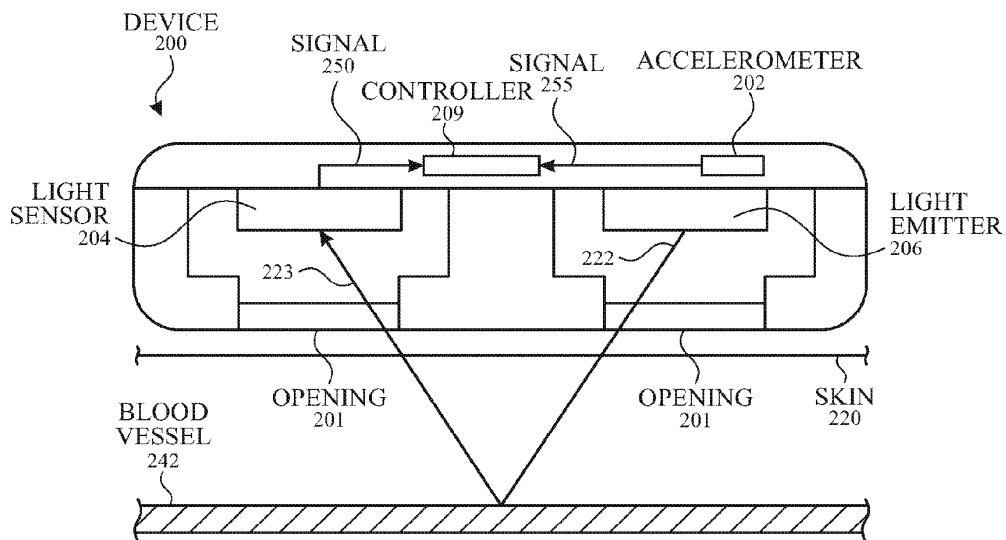


FIG. 2B

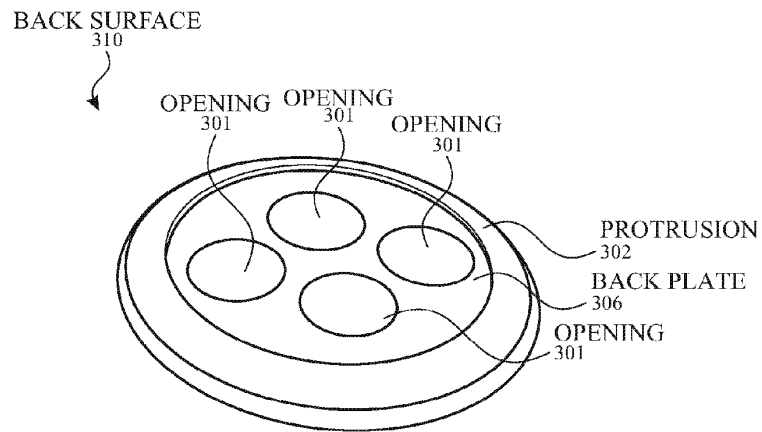


FIG. 3A

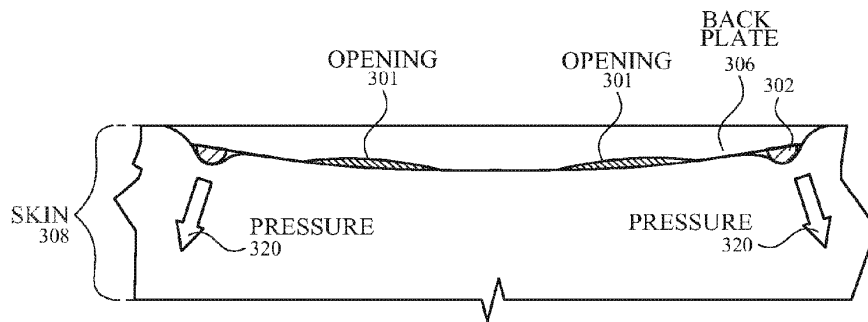


FIG. 3B

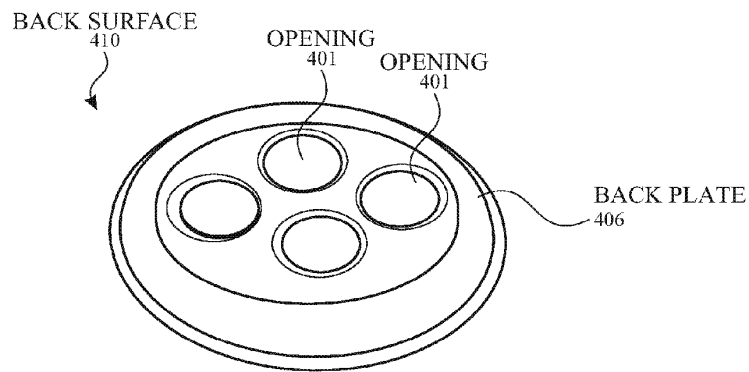


FIG. 4A

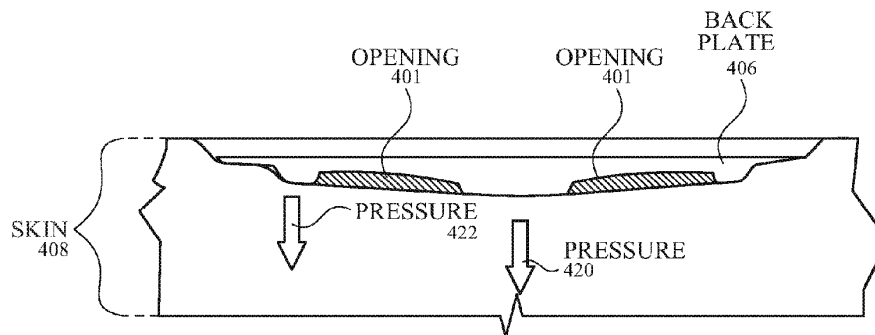


FIG. 4B

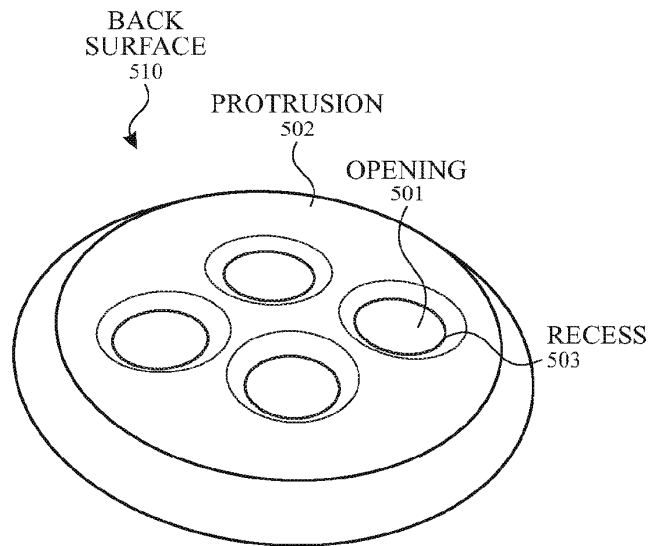


FIG. 5A

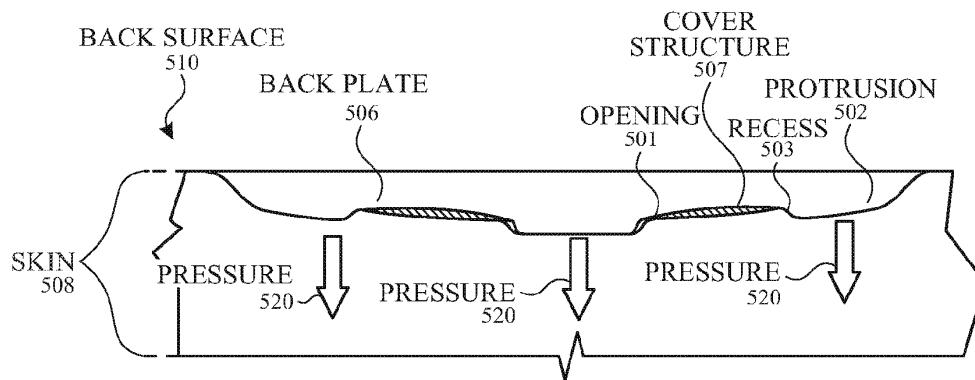


FIG. 5B

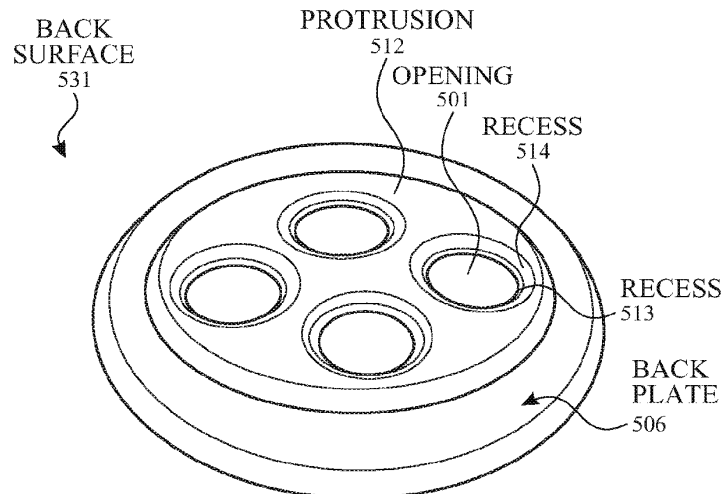


FIG. 5C

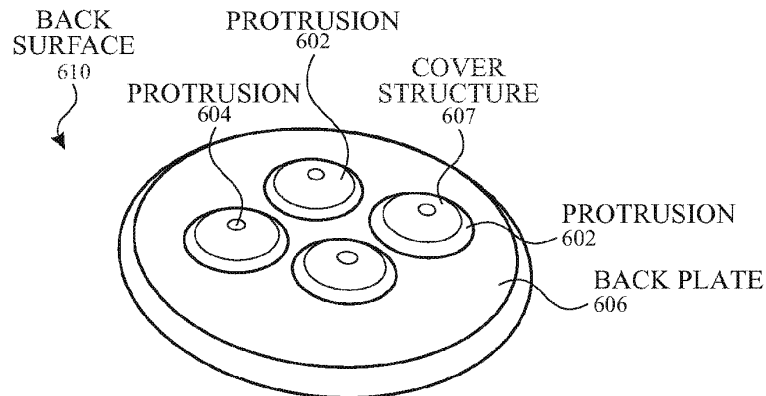


FIG. 6A

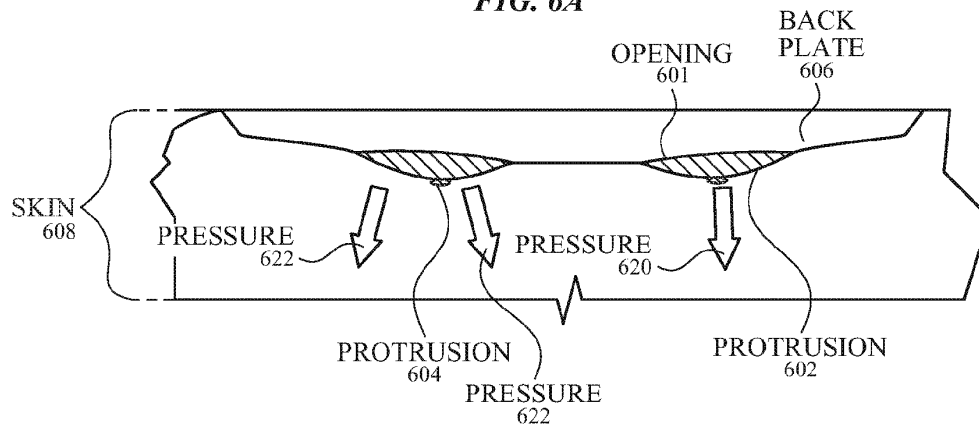


FIG. 6B

PROCESS

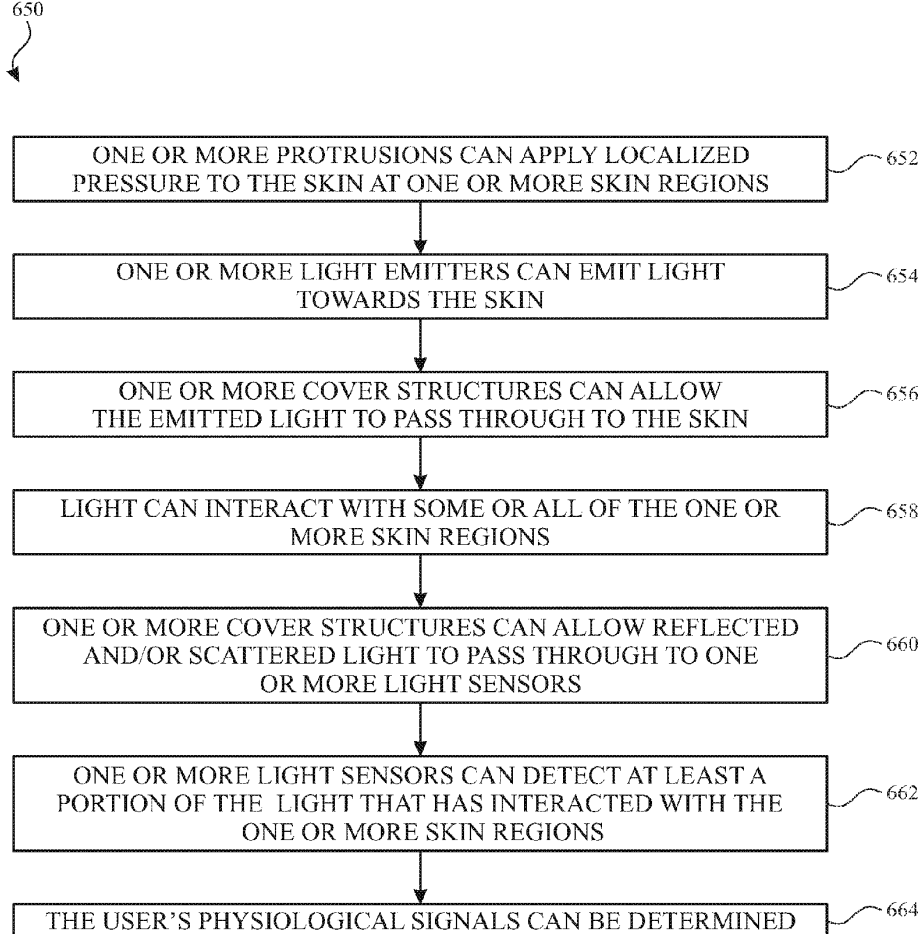


FIG. 6C

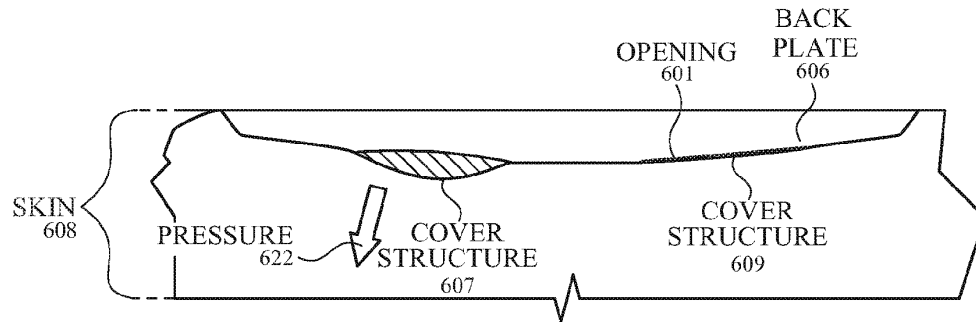


FIG. 6D

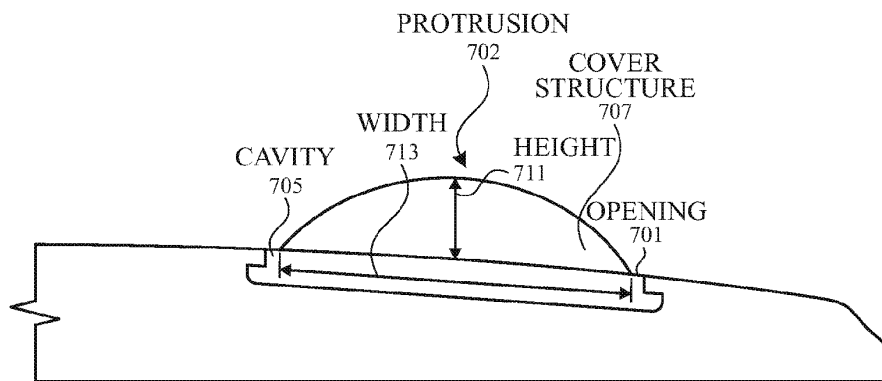


FIG. 7A

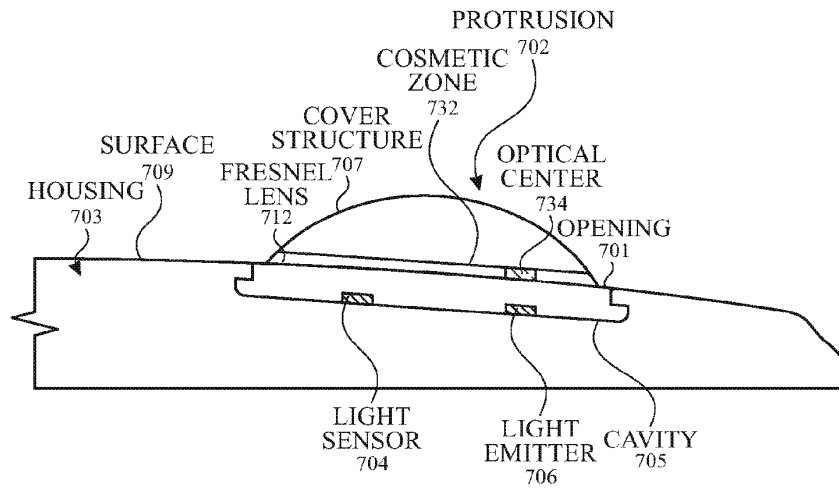


FIG. 7B

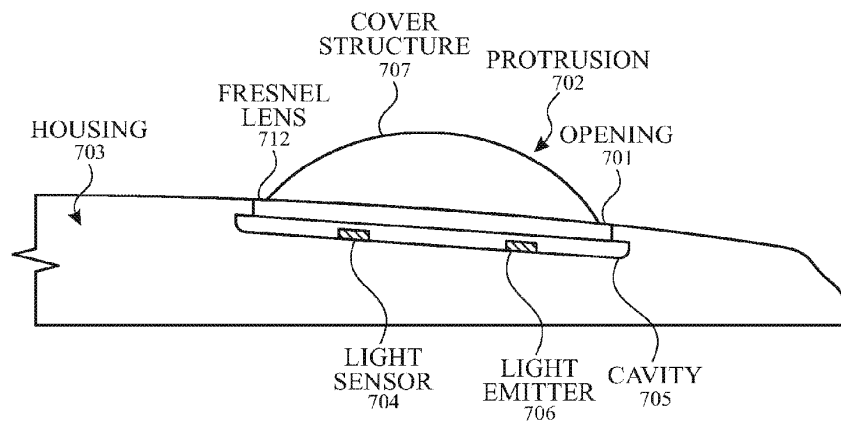


FIG. 7C

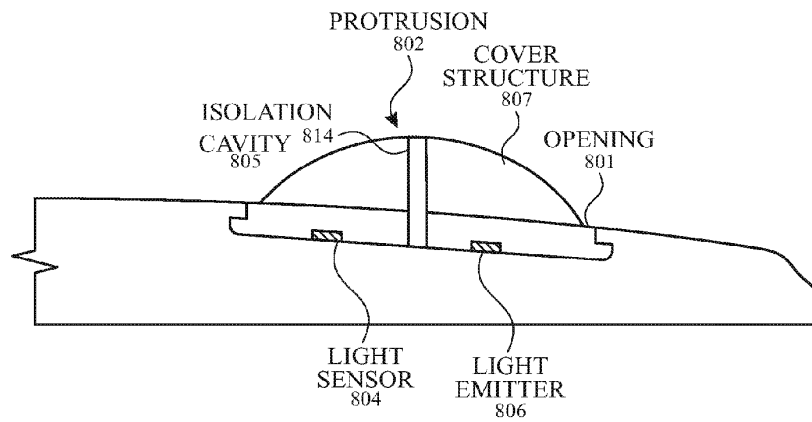


FIG. 8A

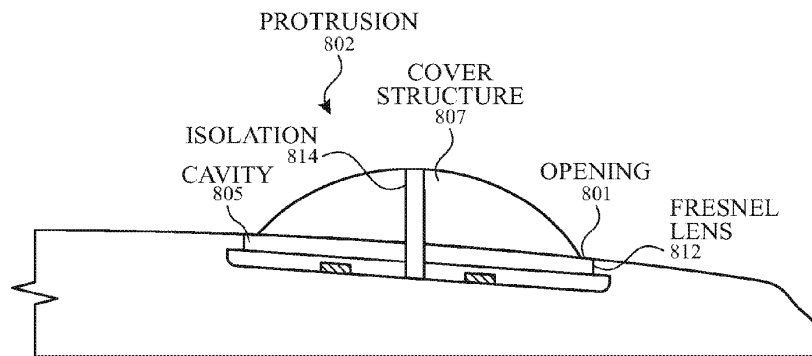
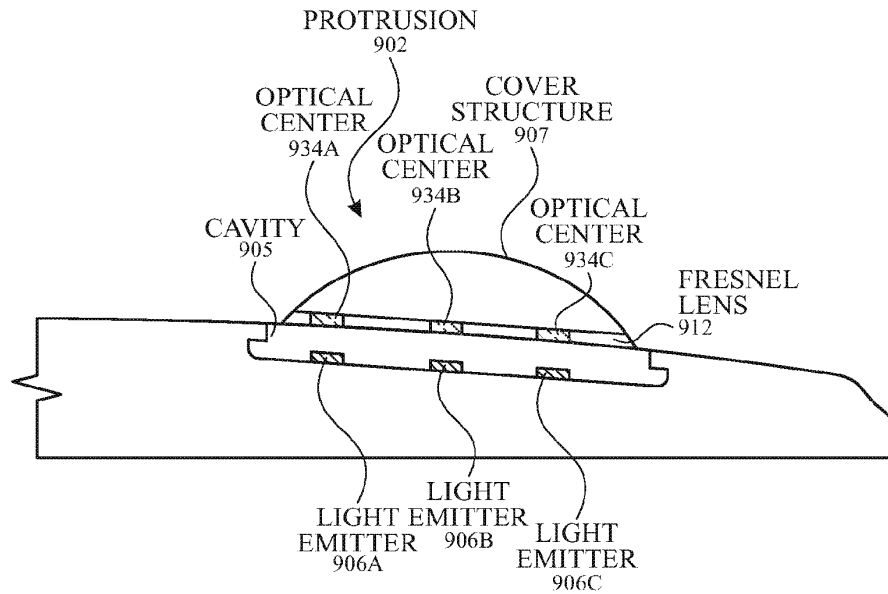
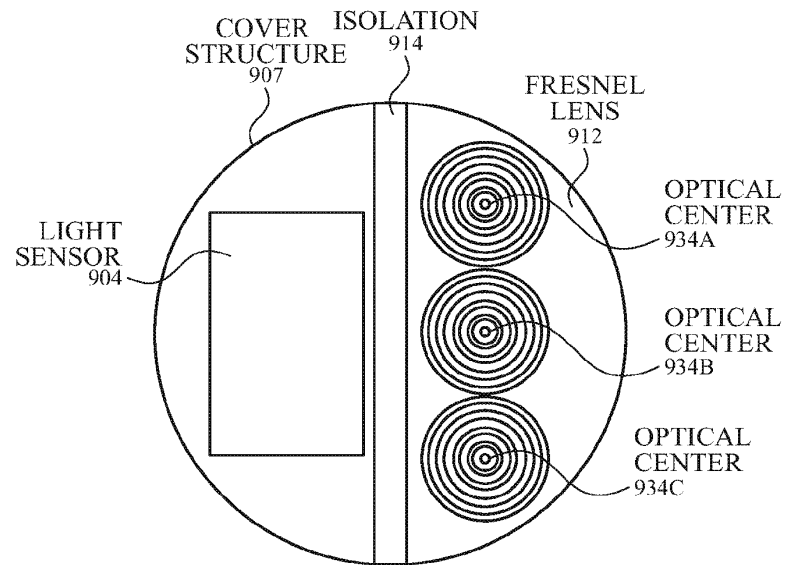


FIG. 8B

**FIG. 9A****FIG. 9B**

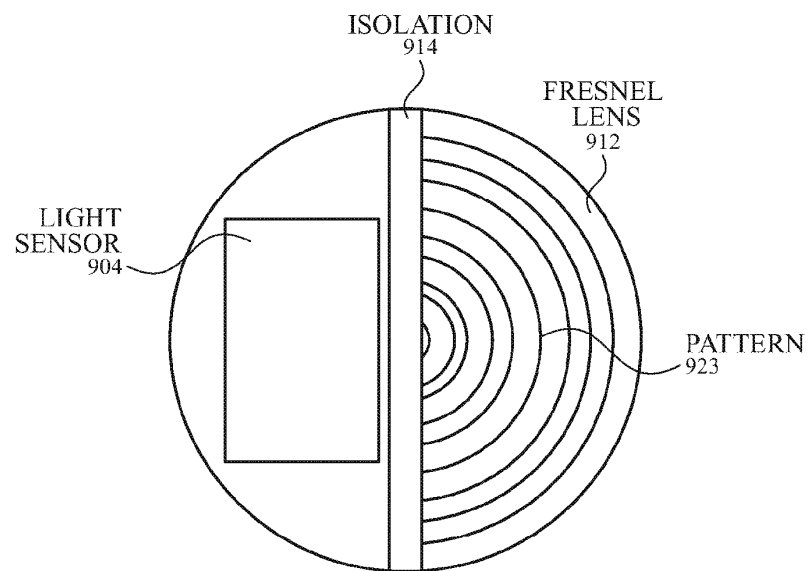


FIG. 9C

PROCESS

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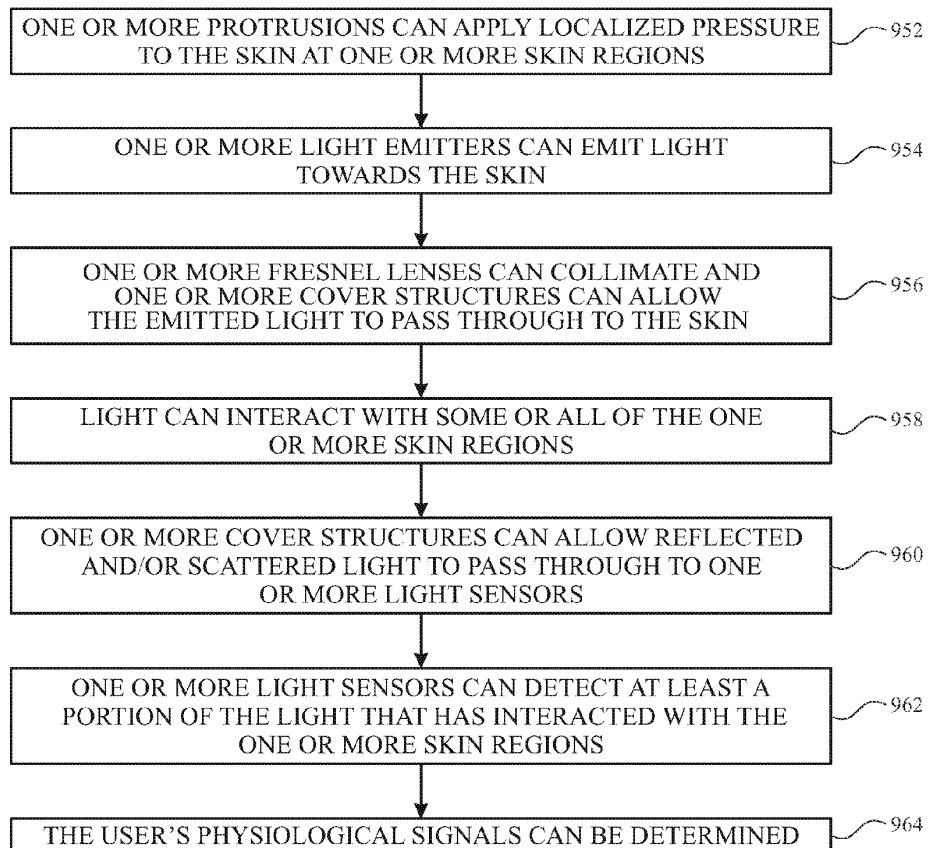


FIG. 9D

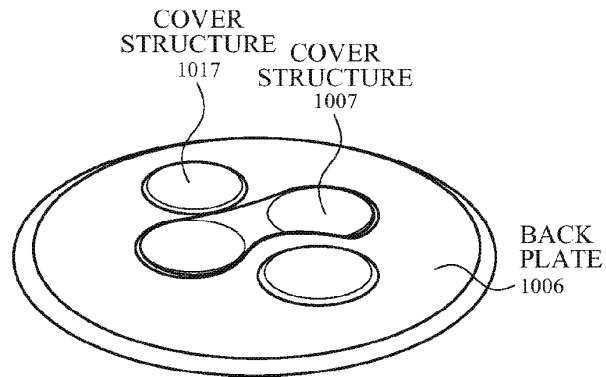


FIG. 10A

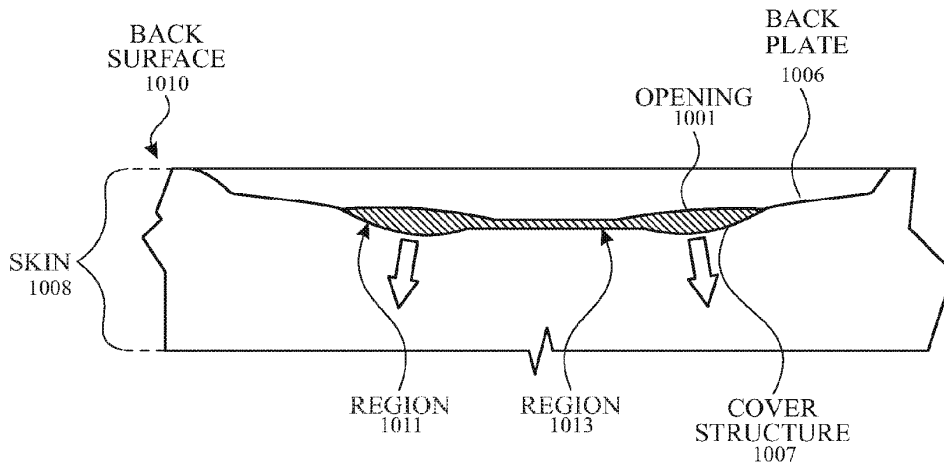


FIG. 10B

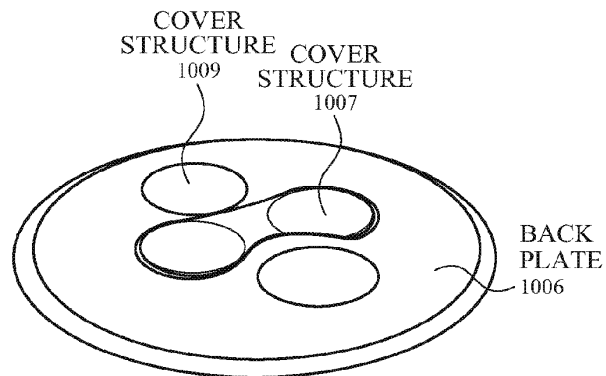
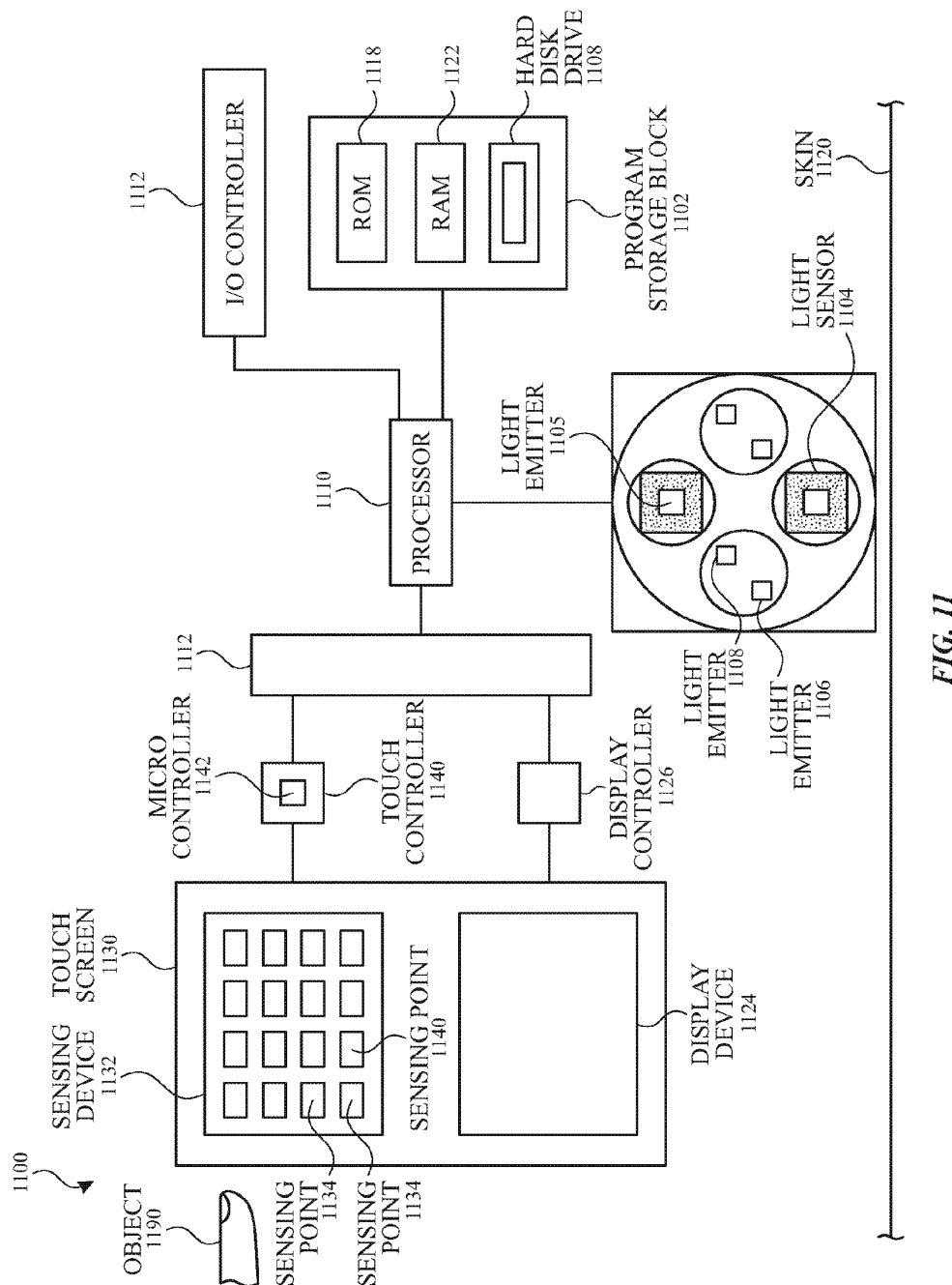


FIG. 10C



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SYSTEMS AND METHODS FOR INCREASING LOCALIZED PRESSURE TO IMPROVE PPG MOTION PERFORMANCE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application Ser. No. 62/397,791 filed on Sep. 21, 2016 and U.S. Provisional Patent Application Ser. No. 62/334,363 filed on May 10, 2016, which are hereby incorporated by reference in their entirety.

FIELD

[0002] This relates to architectures for PPG systems, and more specifically, to PPG systems configured to increasing localized pressure for improving PPG motion performance and methods for operation thereof.

BACKGROUND OF THE DISCLOSURE

[0003] An individual's physiological signals (e.g., pulse rate or arterial oxygen saturation) can be determined by photoplethysmogram (PPG) systems. In a basic form, PPG systems can employ one or more light sources that can illuminate an individual's tissue and one or more light detectors that can receive light that enters and probes a subsurface volume of tissue. The received light can include light with an amplitude that can be modulated in time as a result of interaction with pulsatile blood flow and parasitic, non-signal light that can indirectly sample pulsatile tissue volumes with an amplitude that can be modulated (i.e., "noise" or "artifacts") and/or unmodulated (i.e., DC).

SUMMARY OF THE DISCLOSURE

[0004] This relates to systems and methods for increasing localized pressure to one or more skin regions of an individual. Applying localized pressure to the individual's skin, can lead to increased pulsatile signal, reduced local venous blood volume, and decreased venous contributions to motion artifacts for improved measurement accuracy of the individual's physiological information. The back surface of the device can include one or more protrusions configured to create the localized pressure. In some examples, the protrusion(s) can be located between the optical components (e.g., light sensors and/or light emitters) and one or more edges of the back plate. In some examples, the protrusion(s) can include a surface that can be raised (e.g., forming a plateau surface) relative to the back plate of the device. In some examples, one or more protrusions can include one or more recessed regions. In some examples, the cover structure disposed over each of the openings may itself be a protrusion that can apply local regions of higher pressure directly to the skin regions located in the optical path(s) of the light emitter(s) and/or light sensor(s). The protrusion(s) can be capable of applying localized pressure to multiple (e.g., two) spatially separated regions of the individual's skin. Additionally or alternatively, the protrusion(s) can be capable of applying different amounts of localized pressure. Examples of the disclosure can include the Fresnel lens(es) and/or optical isolation optically coupled to the protrusion.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] FIGS. 1A-1C illustrate systems in which examples of the disclosure can be implemented

[0006] FIG. 2A illustrates a top view, and FIG. 2B illustrates a cross-sectional view of an exemplary electronic device including light sensors and light emitters for measuring an individual's physiological signal according to examples of the disclosure.

[0007] FIGS. 3A-3B illustrate perspective and cross-sectional views of an exemplary back surface of a device including a protrusion located between the optical components and one or more edges of the back plate according to examples of the disclosure.

[0008] FIGS. 4A-4B illustrate perspective and cross-sectional views of an exemplary back surface of a device including a protrusion having a plateau according to examples of the disclosure.

[0009] FIGS. 5A-5B illustrate perspective and cross-sectional views of an exemplary back surface including a recess associated with each cavity and opening of the device according to examples of the disclosure.

[0010] FIG. 5C illustrates a perspective view of an exemplary back surface of a device including a protrusion having multiple recesses associated with each cavity according to examples of the disclosure.

[0011] FIGS. 6A-6B illustrate perspective and cross-sectional views of an exemplary back surface of a device including cover structures that form the protrusions according to examples of the disclosure.

[0012] FIG. 6C illustrates an exemplary method of applying localized pressure to one or more skin regions of the individual according to examples of the disclosure.

[0013] FIG. 6D illustrates a cross-sectional view of an exemplary back surface of a device including cover structures that include protrusions and cover structures that do not include protrusions according to examples of the disclosure.

[0014] FIG. 7A illustrates a cross-sectional view of an exemplary protrusion according to examples of the disclosure.

[0015] FIGS. 7B-7C illustrate cross-sectional views of exemplary protrusions including a Fresnel lens located between the protrusion and cover structure according to examples of the disclosure.

[0016] FIGS. 8A-8B illustrate a cross-sectional view of exemplary protrusions including an isolation according to examples of the disclosure.

[0017] FIGS. 9A-9B illustrate cross-sectional and top views of an exemplary cover structure optically coupled to a plurality of light emitters, an isolation, and a Fresnel lens having multiple optical centers according to examples of the disclosure.

[0018] FIG. 9C illustrates a top view of an exemplary cover structure optically coupled to a plurality of light emitters, an isolation, and a patterned Fresnel lens according to examples of the disclosure.

[0019] FIG. 9D illustrates an exemplary method of applying localized pressure to one or more skin regions of the individual using a device including one or more Fresnel lenses according to examples of the disclosure.

[0020] FIGS. 10A-10B illustrate perspective and cross-sectional views of an exemplary back surface of a device including a monolithic cover structure according to examples of the disclosure.

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[0021] FIG. 10C illustrates a perspective view of an exemplary back surface of a device including a monolithic cover structure that includes protrusions and non-monolithic cover structures that do not include protrusions according to examples of the disclosure.

[0022] FIG. 11 illustrates an exemplary block diagram of a computing system comprising back of cover touch sensor configurations according to examples of the disclosure.

DETAILED DESCRIPTION

[0023] In the following description of examples, reference is made to the accompanying drawings in which it is shown by way of illustration specific examples that can be practiced. It is to be understood that other examples can be used and structural changes can be made without departing from the scope of the various examples.

[0024] Various techniques and process flow steps will be described in detail with reference to examples as illustrated in the accompanying drawings. In the following description, numerous specific details are set forth in order to provide a thorough understanding of one or more aspects and/or features described or referenced herein. It will be apparent, however, to one skilled in the art, that one or more aspects and/or features described or referenced herein may be practiced without some or all of these specific details. In other instances, well-known process steps and/or structures have not been described in detail in order to not obscure some of the aspects and/or features described or referenced herein.

[0025] Further, although process steps or method steps can be described in a sequential order, such processes and methods can be configured to work in any suitable order. In other words, any sequence or order of steps that can be described in the disclosure does not, in and of itself, indicate a requirement that the steps be performed in that order. Further, some steps may be performed simultaneously despite being described or implied as occurring non-simultaneously (e.g., because one step is described after the other step). Moreover, the illustration of a process by its depiction in a drawing does not imply that the illustrated process is exclusive of other variations and modification thereto, does not imply that the illustrated process or any of its steps are necessary to one or more of the examples, and does not imply that the illustrated process is preferred.

[0026] This relates to systems and methods for increasing localized pressure to one or more skin regions of an individual. Applying localized pressure to the individual's skin, can lead to increased pulsatile signal, reduced local venous blood volume, and decreased venous contributions to motion artifacts for improved measurement accuracy of the individual's physiological information. The back surface of the device can include one or more protrusions configured to create the localized pressure. In some examples, the protrusion(s) can be located between the optical components (e.g., light sensors and/or light emitters) and one or more edges of the back plate. In some examples, the protrusion(s) can include a surface that can be raised (e.g., forming a plateau surface) relative to the back plate of the device. In some examples, one or more protrusions can include one or more recessed regions. In some examples, the cover structure disposed over each of the openings may itself be a protrusion that can apply local regions of higher pressure directly to the skin regions located in the optical path(s) of the light emitter(s) and/or light sensor(s). The protrusion(s) can be capable of applying localized pressure to multiple (e.g., two)

spatially separated regions of the individual's skin. Additionally or alternatively, the protrusion(s) can be capable of applying different amounts of localized pressure. Examples of the disclosure can include the Fresnel lens(es) and/or optical isolation optically coupled to the protrusion.

[0027] A user's physiological signals (e.g., pulse rate and arterial blood oxygen saturation) can be determined by measurements using pulse oximetry systems. Such pulse oximetry systems can be designed to be sensitive to changes in the red blood cell number, concentration, volume, or blood oxygen state included in the sample or a user's vasculature. In a basic form, pulse oximetry systems can employ a light source that injects light into the user's tissue and a light detector to receive light that reflects and/or scatters and exits the tissue. In some examples, at least a portion of the photon path length interacts with tissue subsurface structures. Pulse oximetry systems can include, but are not limited to, PPG systems and SpO2 systems. PPG and SpO2 systems can determine signals based on the attenuation of light over time. Attenuation can be due to absorption, and/or scattering resulting from physiological/mechanical changes. Physiological/mechanical changes can include, but are not limited to, red blood cell number, cell/blood volume, red blood cell orientation, red blood cell/blood velocity, shear force, location/spatial distribution, or a combination thereof.

[0028] FIGS. 1A-1C illustrate systems in which examples of the disclosure can be implemented. FIG. 1A illustrates an exemplary mobile telephone 136 that can include a touch screen 124. FIG. 1B illustrates an exemplary media player 140 that can include a touch screen 126. FIG. 1C illustrates an exemplary wearable device 144 that can include a touch screen 128 and can be attached to an individual using a strap 146. The systems of FIGS. 1A-1C can include systems and methods for increasing localized pressure, as will be disclosed.

[0029] FIG. 2A illustrates a top view, and FIG. 2B illustrates a cross-sectional view of an exemplary electronic device including light sensors and light emitters for measuring an individual's physiological signal according to examples of the disclosure. The top view in FIG. 2A can be viewed as the underside of a wearable device (e.g., wearable device 144 of FIG. 1C). Device 200 can include light sensor 204, light sensor 214, light emitter 206, and light emitter 216. Light sensor 204 can be optically coupled to light emitter 206 and light emitter 216. Light sensor 214 can be optically coupled to light emitter 206 and light emitter 216. Device 200 can be situated such that light sensor 204, light sensor 214, light emitter 206, and light emitter 216 are proximate to the skin 220 of an individual. For example, device 200 can be held in an individual's hand or strapped to an individual's wrist, among other possibilities.

[0030] Light emitter 206 can be configured to emit light (e.g., light 222), included in one or more light rays, through opening 201. A portion of the one or more light rays can be absorbed by one or more blood vessels 242, and a portion of the one or more light paths can reflect back through opening 201 to be detected by a light sensor. For example, as illustrated in FIG. 2B, a portion of light 222 (emitted by light emitter 206) can be absorbed by blood vessel 242, and a portion of light (e.g., light 223) can reflect back for detection by light sensor 204. Light emitter 206 can also be configured to emit light, and a portion of light can reflect back for

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detection by light sensor **214**. Similarly, light emitter **216** can be configured to emit light towards light sensor **204** and light sensor **214**.

[0031] Light sensor **204** can be configured to generate signal **250**. Signal **250** can include the measured total signal (e.g., sum of the measured modulated light and unmodulated light) detected by the light sensor (e.g., light sensor **204**). In some examples, the device or system can include an accelerometer **202**. Accelerometer **202** can be any type of sensor capable of measuring acceleration and can be configured to generate signal **255** indicative of the measured acceleration. Device **200** can include a processor or controller **209** configured to determine the individual's physiological signal from signal **250** and signal **255**. The individual's physiological signal can be determined using any number of algorithms or simple mathematical functions including, but not limited to, subtracting, multiplying, and/or scaling.

[0032] In some instances, the signal (e.g., signal **250**) can include noise due to motion artifacts, for example. As the individual moves, internal motion (e.g., the skin, vasculature, and other parts of the body expanding and contracting) can contribute to the motion artifacts. To improve motion performance, localized pressure can be created at the individual's skin by the one or more protrusions of the device. The one or more protrusions can be, for example, one or more rigid structures. In some examples, the applied pressure can be directly situated in the optical path (formed by the light emitter(s) and light sensor(s)). By applying localized pressure to the individual's skin, the pressure gradient across arterial walls can be reduced, which can lead to an increase in pulsatile (AC) signal. Additionally, the localized pressure can allow blood to mobilize out of the high-pressure region(s), which can reduce the local venous volume. Venous blood can be non-pulsatile blood that can absorb light, leading to reduced signal levels. In some instances, the DC signal measured by the light sensor(s) can increase, and the venous contributions to motion artifacts can be reduced. With increased pulsatile (DC) signal levels, the measured signal can include less noise, and signal-to-noise ratios can increase. Further, with increased pulsatile signal levels, the power consumption of the device can decrease without compromising measurement accuracy.

[0033] The device can include a back plate located on the back surface of the device. The back plate can include one or more structures (e.g., rigid structures) configured to create localized pressure (i.e., pressure in one or more regions of the individual's skin, where the area of the pressurized region can be smaller than the area of the back surface and/or back plate of the device). The one or more structures can include one or more protrusions having area(s) smaller than the area of the back plate. The one or more protrusions can be, for example, one or more rigid structures. In some examples, the one or more structures can include one or more protrusions located between the optical components (e.g., light sensors and/or light emitters) and one or more edges of the back plate. FIGS. 3A-3B illustrate perspective and cross-sectional views of an exemplary back surface of a device including a protrusion located between the optical components and one or more edges of the back plate according to examples of the disclosure. Back surface **310** of the device can include back plate **306** and protrusion **302**. Protrusion **302** can be configured to create pressure to skin **308**. Protrusion **302** can apply a greater amount of pressure

320 in a surrounding region (e.g., circular region) than the pressure created at other regions (e.g., region under openings **301**) of skin **308**.

[0034] Protrusion **302** can at least partially surround openings **301**. In some examples, openings **301** can be configured to allow light emitted from a light emitter (e.g., light emitter **206** illustrated in FIG. 2A) to pass through to skin **308** and/or can allow light reflected from skin **308** to pass through to a light sensor (e.g., light sensor **204** illustrated in FIG. 2A). One or more optical components (e.g., light emitter(s), light sensor(s), or a combination thereof) can be located within the housing of the device and can be aligned with an opening **301** of a corresponding cavity. A transparent or translucent cover structure can be disposed over or within each of the openings **301** or cavities.

[0035] In some examples, protrusion **302** can be the same shape as back plate **306**. For example, protrusion can be ring-shaped, which can include an open or closed ring (e.g., located around all edges of the device). In some examples, the protrusion can be arc-shaped. In some examples, protrusion **302** can surround all of openings **301** and corresponding cavities. Alternatively, back surface **310** can include a first protrusion that can surround a first set of cavities and a second protrusion that can surround a second set of cavities. In some examples, the protrusion may not surround or enclose any of the cavities, but instead can span a length or width of back surface **310** (not shown) (e.g., a rectangular protrusion parallel to one or more edges of the device).

[0036] Protrusion **302** can be disposed back plate **306**. Protrusion **302** can protrude out from back surface **310** and/or back plate **306** such that pressure **320** can be created at skin **308** in one or more regions surrounding protrusion **302**. Back plate **306** can be, for example, one or more rigid structures. In some examples, protrusion **302** can be configured to create localized pressure **320** to multiple (e.g., two) spatially separated regions of skin **308**, as illustrated in FIG. 3B; wherein multiple optical components and/or the optical paths can be located between the spatially separated regions. In some examples, back plate **306** can have a convex curvature (as illustrated in FIG. 3B) or a concave curvature (not shown). In some examples, back plate **306** may not have any curves and may be substantially flat. In some examples, protrusion **302** can be embedded or disposed on back plate **306**. In some examples, protrusion **302** can be a separate structure that can be adhered (e.g., using an adhesive) to back plate **306** and/or can protrude from back plate **306**.

[0037] In some examples, pressure can be applied closer to the optical paths of the optical components and/or over a larger region(s) of the individual's skin. FIGS. 4A-4B illustrate perspective and cross-sectional views of an exemplary back surface of a device capable of creating multiple levels of localized pressure using a back plate according to examples of the disclosure. Back surface **410** can include back plate **406** and a plurality of openings **401**. The plurality of openings **401** can be configured to allow light emitted from a light emitter (e.g., light emitter **206** illustrated in FIG. 2A) to pass through to skin **408** and/or can allow light reflected from skin **408** to pass through to a light sensor (e.g., light sensor **204** illustrated in FIG. 2A). One or more optical components (e.g., light emitter(s), light sensor(s), or a combination thereof) can be located within the housing of the device and can be aligned with an opening **401** of a corre-

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sponding cavity. A transparent or translucent cover structure (e.g., window) can be disposed over or within each of the openings 401 or cavities.

[0038] Back plate 406 can include a plurality of sections that extend from back surface 410, where the plurality of sections can have different heights. In some examples, the surface of back plate 406 can be flat (i.e., without any curvature or curves) (not shown). In some examples, the surface of back plate 406 can have a convex curvature, as illustrated in FIG. 4B. The curvature can create the different heights such that multiple levels of localized pressure (e.g., pressure 420 and pressure 422) can be created. The cover structures (e.g., windows) disposed over or within openings 401 and can be flush with the surface of back plate 406 where back plate 406 joins (or forms) the cover structures. In some examples, the cover structures can protrude even further from the surface of back plate 406. In some examples, one or more cover structures can be separate and distinct from the back plate, and an adhesive, for example, can be used to adhere the cover structure(s) to the back plate and/or back surface. In some examples, one or more cover structure(s) can be integrated into the back plate.

[0039] Although FIG. 4A illustrates back plate 406 as having a circular shape, examples of the disclosure can include a back plate with any shape (e.g., ellipse, oval, rectangle, etc.). In some examples, back surface 410 can include two or more raised regions or protrusions that can be co-located with openings 401. For example, a back surface can include a first semi-circular protrusion that can extend over portions of the back surface that include a subset of one or more cavities and/or corresponding openings. The back surface can also include another subset of one or more cavities and/or corresponding openings. Examples of the disclosure can further include one or more cover structures that include an isolation, as discussed below.

[0040] The cavities (including light emitter(s) and/or light sensor(s) and corresponding openings) can be located at least partially on back plate 406. For example, back plate 406 can form a plateau that can extend from the edges of the device to the openings 401. In some examples, at least a portion of the corresponding cavities can be located on the surface of the plateau. Back plate 406 can extend over or across a substantial portion of the area of the back surface (e.g., the surface area of the plateau can be about 30%, 40%, 50%, 60% or more of the surface area of the entire back surface).

[0041] In some examples, one or more protrusions can include one or more recessed regions, the one or more recessed regions can include the opening and/or cover structures. FIGS. 5A-5B illustrate perspective and cross-sectional views of an exemplary back surface including a recess associated with each cavity and opening of the device according to examples of the disclosure. Back surface 510 can include protrusion 502, which can include recesses (i.e., recessed regions) 503. Recesses 503 can be each located over opening 501. That is, one or more cavities and corresponding light emitter(s) and/or light sensor(s) can be located within recess 503.

[0042] A cover structure 507 can be located within each cavity. In some examples, cover structure 507 can be set within each recess 503 such that the cover structure 507 may not be flush with (i.e., does not extend beyond) the surface of protrusion 502. In some examples, cover structure 507 can also be recessed from protrusion 502. Protrusion 502 can

create greater levels of pressure 520 to skin regions compared to recesses 503, openings 501, and/or cover structures 507. In this manner, protrusion 502 can be configured to create localized pressure 320 to multiple (e.g., three) spatially separated regions of skin 308, as illustrated in FIG. 5B; wherein the spatially separated regions can include at least one region located between the optical components.

[0043] In some examples, the protrusion including recesses can have less surface area. In some examples, the device can be capable of applying multiple levels of localized pressure. FIG. 5C illustrates a perspective view of an exemplary back surface of a device including a protrusion having multiple recesses associated with each cavity according to examples of the disclosure. Back surface 531 can include protrusion 512. Protrusion 512 can include recess 513 and recess 514. Recess 513 can have a first depth (relative to the back surface of the back plate), and recess 514 can have a second depth (relative to the back surface of the back plate), the second depth being less than the first depth. Due to the differences in depths, protrusion can apply a greater amount of pressure to the individual's skin than either of the recesses. Recess 514 can apply a greater amount of pressure to the individual's skin than recess 513. In some examples, the surface area of protrusion 512 can be about 20% less, 30% less, 40% less, or 50% less than the surface area of protrusion 502 illustrated in FIGS. 5A-5B. In some examples, cover structure 507 can be recessed with respect to the back surface of the back plate, as shown in FIG. 5B. In some examples, one or more cover structures can be separate and distinct from the back plate, and an adhesive, for example, can be used to adhere the cover structure(s) to the back plate and/or back surface. In some examples, one or more cover structure(s) can be integrated into the back plate.

[0044] For example, the back surface can include one or more cavities having a corresponding opening and a protrusion located over each of the openings. In some examples, the cover structure disposed over each of the openings may itself be a protrusion that can apply local regions of higher pressure directly to the skin regions located in the optical path(s) of the light emitter(s) and/or light sensor(s). In other words, the skin region(s) that may be subject to increased levels of pressure may co-localize with the illumination field(s) of the one or more light emitter(s) and/or the field-of-view(s) of the one or more sensors. In some examples, the cover structures themselves can form protrusions. FIGS. 6A-6B illustrate perspective and cross-sectional views of an exemplary back surface of a device including cover structures that form the protrusions according to examples of the disclosure. Back surface 610 can include openings 601 and cover structures 607. Cover structures 607 can protrude from the surface of back plate 606. Back plate 606 can be, for example, one or more rigid structures. Cover structures 607 can include an optically transparent or translucent material such as acrylic, glass, and the like.

[0045] In some examples, multiple levels of localized pressure can be applied by the cover structures. Cover structures 607 can include one or more protrusions: protrusion 602 and, optionally, protrusion 604, where protrusion 602 can have a lower height (relative to the outward surface (i.e., surface facing skin 508 and/or external surface of the housing of the device) of the cover structure) than protrusion 604. In some examples, protrusion 604 can be located in the

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optical center of cover structure 607. The one or more protrusions (including the cover structure themselves) can be, for example, one or more rigid structures. In some examples, one or more cover structures can be separate and distinct from the back plate, and an adhesive, for example, can be used to adhere the cover structure(s) to the back plate and/or back surface. In some examples, one or more cover structure(s) can be integrated into the back plate.

[0046] Skin regions located under protrusion 602 can be subject to greater amounts of pressure 622 compared to skin regions located under non-protruding (e.g., back plate 606) portions of back surface 610. The radius of curvature of cover structures 602 can be consistent across the surface of the protrusion 602 (i.e., the curvature of a protrusion can approximate the curvature of a sphere). In some examples, the radius of curvature of cover structures 602 can vary (i.e., the curvature of a protrusion can be similar to the curvature of an oval). Skin regions located under protrusion 604 can be subject to greater amounts of pressure 620 compared to skin regions located under protrusion 602. In this manner, the localized pressure 620 and 622 can both be located in the optical path and/or field-of-view of the light emitter(s) and/or light sensor(s). In some examples, back plate can include one or more protrusions having a third height, where the third height can be less than the height of protrusion 602 and protrusion 604. That is, the back surface of the device can include three protrusions, each having different heights and configured to create different amounts of pressure.

[0047] FIG. 6C illustrates an exemplary method of applying localized pressure to one or more skin regions of the individual according to examples of the disclosure. One or more protrusions (e.g., protrusion 302 illustrated in FIGS. 3A-3B, back plate 406 illustrated in FIGS. 4A-4B, protrusion 502 illustrated in FIGS. 5A-5B, protrusion 512 illustrated in FIG. 5C, and protrusion 602 illustrated in FIGS. 6A-6B) can apply localized pressure (e.g., pressure 320 illustrated in FIG. 3B, pressure 420 illustrated in FIG. 4B, pressure 520 illustrated in FIG. 5B, and pressure 620 and pressure 622 illustrated in FIG. 6B) to the individual's skin (e.g., skin 220 illustrated in FIG. 3B, skin 308 illustrated in FIG. 3B, skin 408 illustrated in FIG. 4B, skin 508 illustrated in FIG. 5B, and skin 608 illustrated in FIG. 6B) at one or more skin regions (step 652 of process 650).

[0048] In some examples, the localized pressure can be created at multiple spatially separated regions of the individual's skin. In some examples, the localized pressure can be created at regions of the individual's skin located outside of the optical paths and/or field-of-view of the light emitter(s) and/or light sensor(s). In some examples, the localized pressure can be created at regions of the individual's skin in the optical paths and/or field-of-view of the light emitter(s) and/or light sensor(s). In some examples, the applied localized pressure can include different amounts of localized pressure. In some examples, the different amounts of localized pressure can be created by a protrusion disposed on the back plate, one or more recesses associated with a cavity, and/or one or more protrusions disposed on a cover structure.

[0049] One or more light emitters (e.g., light emitter 206 and light emitter 216 illustrated in FIG. 2A) can emit light towards the individual's skin (step 654 of process 650). One or more cover structures (e.g., cover structure 507 illustrated in FIG. 5B and cover structure 607 illustrated in FIG. 6A) can allow the emitted light to pass through to the individual's

skin (step 656 of process 650). Light can interact with some or all of the one or more skin regions (step 658 of process 650) and can reflect and/or scatter back to the device. One more cover structures can allow reflected and/or scattered light to pass through to one or more light sensors (e.g., light sensor 204 and light sensor 214 illustrated in FIG. 2A) (step 660 of process 650). One or more light sensors can detect at least a portion of the light that has interacted with the one or more skin regions (step 662 of process 650). A processor or controller (e.g., controller 209) can determine the individual's physiological signals (step 664 of process 650).

[0050] The device can include any number of protrusions coupled to the one or more cover structures. In some example, some, but not all, of the cover structures can be associated with a protrusion. FIG. 6D illustrates a cross-sectional view of an exemplary back surface of a device including cover structures that include protrusions and cover structures that do not include protrusions according to examples of the disclosure. The device can include cover structure 607 and cover structure 609. Cover structure 607 can include a protrusion to create localized pressure in one or more regions of skin 608. Cover structure 609 may not include a protrusion and may not create localized pressure. Cover structure 609 can be flush (i.e., not protrude) from back plate 606. In some examples, cover structure 609 can be recessed with respect to back plate 606. In some examples, one or more cover structures can be separate and distinct from the back plate, and an adhesive, for example, can be used to adhere the cover structure(s) to the back plate and/or back surface. In some examples, one or more cover structure(s) can be integrated into the back plate.

[0051] Examples of the disclosure can include cover structure 607 optically coupled to a different type of optical component than cover structure 609 can be optically coupled to. For example, cover structure 607 can be optically coupled to one or more light emitters, whereas cover structure 609 can be optically coupled to one or more light sensors.

[0052] In some examples, the height and/or curvature of one or more protrusions on the back surface of a device can vary, as may be desired, to attain a desired pressure profile in the individual's skin. FIG. 7A illustrates a cross-sectional view of an exemplary protrusion according to examples of the disclosure. Protrusion 702 can be located over opening 701 of a cavity 705. In some examples, protrusion 702 can include the cover structure 707 (e.g., window) disposed over opening 701. Protrusion 702 can have a height 711 that can be between 0.3-2 mm. In some examples, height 711 can be 0.5 mm, 0.9 mm, 1.1 mm, or 1.3 mm. Protrusion 702 can have a radius of curvature that can be between 2.5-8.5 mm. In some examples, the radius of curvature can be 3.23 mm, 3.43 mm, 4.25 mm, 4.47 mm, 6.4 mm, or 7.47 mm. Protrusion 702 can have a base width 713 that can span the width of opening 701. In some examples, base width 713 can be less than the width of opening 701. In some examples, base width 713 can be between 3-10 mm. In some examples, base width 713 can be 3.5 mm, 4.5 mm, 5.4 mm, 6 mm, 7.3 mm, or 8.8 mm.

[0053] In some examples, the cover structure and/or protrusion can include a Fresnel lens or a similar optical component. In some instances, it may be desirable to obscure the optical components (e.g., light sensor(s) and/or light emitter(s)) and to reduce perceptibility of the optical

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components by an individual. In addition to obscuring internal components, it may be desirable for light emitted by the light emitter to retain its optical power, collection efficiency, beam shape, and collection area such that the light undergoes minimal change due to the cover structure. Examples of the disclosure can include the Fresnel lens(es) located in the protrusion.

[0054] In some examples, the Fresnel lens(es) can be located between the protrusion and cover structure, as illustrated in FIG. 7B. Fresnel lens **712** can be located between protrusion **702** and light emitter **706**, which can be located in cavity **705**. Fresnel lens **712** can be located above opening **701** of cavity **705**, where cavity **705** can be recessed from the surface **709** of housing **703**. Fresnel lens **712** can have multiple regions, such as an optical center **734** and a cosmetic zone **732**. Optical center **734** can be placed in a same region or location as light emitter **706** and can be configured to collimate light emitted by light emitter **706** into a smaller beam size, for example. Cosmetic zone **732** can be located in regions outside of optical center **734**. Cosmetic zone **732** can include one or more ridges to help obscure the underlying internal components.

[0055] Optionally, a light sensor **704** can be optically coupled to Fresnel lens **712**. In some examples, light sensor **704** can be disposed in the same cavity **705** as light emitter **706**. In some examples, light sensor **704** can be optically coupled to a different Fresnel lens (than light emitter **706**). The different Fresnel lens may not have an optical center (e.g., because a light sensor may be a large area photodiode that may not require shaping of the light field), but can include a cosmetic zone having one or more ridges. The ridges can include, for example, saw tooth patterns, cylindrical ridges, asymmetric shapes, and wavy shape (i.e., ridges that move in an out).

[0056] Fresnel lens **712** may be used, additionally or alternatively, for light collimation. By collimating light, the optical efficiency can be improved. Without a lens or similar collimating optical element, emitted light may be directed at an angle away from the light sensor and can be lost. In some examples, light may be directed at an angle toward the light sensor, but the angle may be shallow (e.g., less than 15°). Fresnel lens **712** can redirect light to one or more directions to prevent light from being lost or entering into the skin at shallow angles. Such redirected light can be collected instead of being lost and/or may militate against parasitic non-signal light, which can improve optical signal efficiency. In some examples, a diffusing agent can be used in addition to (or instead of) a Fresnel lens. A diffusing agent can be surrounding, touching, and/or covering one or more components of the light emitter. In some examples, diffusing agent can be a resin or epoxy that encapsulates the dies (or any other components) and/or wire bonds. Diffusing agent can be used to adjust the angle(s) of light emitted by the light emitter. By narrowing the beam of emitted light, more light can be collected by the lens and/or window, and a larger amount of light can be detected by the light sensor. In some examples, Fresnel lens(es) can be located within the opening **701** of cavity **705** (e.g., with housing **703**), as illustrated in FIG. 7C.

[0057] In some examples, one or more protrusions can include an isolation that can extend through the protrusion, where the isolation can be configured to separate light rays of the optical components on one side of the protrusion and/or cover structure from light rays on the other side. The

isolation can extend from within the cavity, through the cavity, and/or through the protrusion. FIG. 8A illustrates a cross-sectional view of an exemplary protrusion including an isolation according to examples of the disclosure. Protrusion **802** can be disposed over opening **801** of cavity **805**. Protrusion **802** can include an isolation **814**, which can extend through the protrusion. In some examples, isolation **814** can extend inside (e.g., to the base of) cavity **805**. While the figure illustrates isolation **814** as being substantially perpendicular to the base of cavity **805**, examples of the disclosure can include isolation **814** having a non-perpendicular angle with respect to the base of cavity **805**. In some examples, protrusion **802** can be included in cover structure **807**, which can be coupled to light sensor **804** and light emitter **806**. In some examples, protrusion **802** can include an isolation and can be optically coupled to a Fresnel lens, as illustrated in FIG. 8B. Fresnel lens **812** can include one or more designs and/or operation similar to Fresnel lens **712** illustrated in FIGS. 7B-7C and discussed above.

[0058] In some examples, the isolation can be located in the one or more cover structures, and the device can further comprise one or more separate structures including the one or more protrusions (having the same features, design, and/or operation as described above). In some examples, both the cover structures and the separate structures can include protrusions.

[0059] In some examples, the protrusion and/or cover structure can be optically coupled to a Fresnel lens having multiple optical centers. FIGS. 9A-9B illustrate cross-sectional and top views of an exemplary cover structure optically coupled to a plurality of light emitters, an isolation, and a Fresnel lens having multiple optical centers according to examples of the disclosure. Protrusion **902** can be included in cover structure **907**. Cover structure **907** can be optically coupled to light emitter **906A**, light emitter **906B**, and light emitter **906C** located in cavity **905**. In some examples, light sensor **904** can be disposed in the same cavity **905** as the light emitters. In some examples, isolation **914** can provide an optical barrier between light sensor **904** and the plurality of light emitters (e.g., light emitter **906A**, light emitter **906B**, and light emitter **906C**).

[0060] Fresnel lens **912** can be located between the plurality of light emitters and protrusion **902**. Fresnel lens can include a plurality of optical centers, such as optical center **934A**, optical center **934B**, and optical center **934C**. Optical center **934A** can be optically coupled to light emitter **906A**; optical center **934B** can be optically coupled to light emitter **906B**; and optical center **934C** can be optically coupled to light emitter **906C**. In some examples, the center of each optical center can be located over (e.g., aligned with) the center of its corresponding light emitter. In some examples, the ridge pattern of each optical center can include a plurality of concentric rings, spirals, semicircles, and/or arcs (e.g., pattern **923** illustrated in FIG. 9C). Examples of the disclosure can include one or more Fresnel lenses located in the cover structure, and/or underneath the housing (e.g., within the volume enclosed by the housing). In some examples, the plurality of light emitters may not be collinearly arranged (e.g., can be offset with respect to each other), and the optical centers of the Fresnel lens can be arranged to correspond to the positions of the plurality of light emitters.

[0061] FIG. 9D illustrates an exemplary method of applying localized pressure to one or more skin regions of the

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individual using a device including one or more Fresnel lenses according to examples of the disclosure. One or more protrusions (e.g., protrusion **302** illustrated in FIGS. **3A-3B**, back plate **406** illustrated in FIGS. **4A-4B**, protrusion **502** illustrated in FIGS. **5A-5B**, protrusion **512** illustrated in FIG. **5C**, protrusion **602** illustrated in FIGS. **6A-6B**, protrusion **702** illustrated in FIGS. **7A-7C**, protrusion **802** illustrated in FIGS. **8A-8B**, and protrusion **902** illustrated in FIG. **9A**) can apply localized pressure (e.g., pressure **320** illustrated in FIG. **3B**, pressure **420** illustrated in FIG. **4B**, pressure **520** illustrated in FIG. **5B**, and pressure **620** and pressure **622** illustrated in FIG. **6B**) to the individual's skin (e.g., skin **220** illustrated in FIG. **3B**, skin **308** illustrated in FIG. **3B**, skin **408** illustrated in FIG. **4B**, skin **508** illustrated in FIG. **5B**, and skin **608** illustrated in FIG. **6B**) at one or more skin regions (step **952** of process **950**).

[0062] In some examples, the localized pressure can be created at multiple spatially separated regions of the individual's skin. In some examples, the localized pressure can be created at regions of the individual's skin located outside of the optical paths and/or field-of-view of the light emitter(s) and/or light sensor(s). In some examples, the localized pressure can be created at regions of the individual's skin in the optical paths and/or field-of-view of the light emitter(s) and/or light sensor(s). In some examples, the applied localized pressure can include different amounts of localized pressure. In some examples, the different amounts of localized pressure can be applied by a protrusion disposed on the back plate, one or more recesses associated with a cavity, and/or one or more protrusions disposed on a cover structure.

[0063] One or more light emitters (e.g., light emitter **206** and light emitter **216** illustrated in FIG. **2A**) can emit light towards the individual's skin (step **954** of process **950**). One or more Fresnel lenses (e.g., Fresnel lens **712** illustrated in FIGS. **7B-7C**, Fresnel lens **812** illustrated in FIG. **8B**, and Fresnel lens **912** illustrated in FIGS. **9A-9C**) and one or more cover structures (e.g., cover structure **507** illustrated in FIG. **5B**, cover structure **607** illustrated in FIG. **6A**, cover structure **707** illustrated in FIGS. **7B-7C**, cover structure **807** illustrated in FIG. **8B**, and cover structure **907** illustrated in FIG. **9A**) can allow the emitted light to pass through to the individual's skin (step **956** of process **950**). Light can interact with some or all of the one or more skin regions (step **958** of process **950**) and can reflect and/or scatter back to the device. One more cover structures can allow reflected and/or scattered light to pass through to one or more light sensors (e.g., light sensor **204** and light sensor **214** illustrated in FIG. **2A**) (step **960** of process **950**). One or more light sensors can detect at least a portion of the light that has interacted with the one or more skin regions (step **962** of process **950**). A processor or controller (e.g., controller **209**) can determine the individual's physiological signals (step **964** of process **950**).

[0064] In some examples, one or more cover structures can be monolithic cover structures. FIGS. **10A-10B** illustrate perspective and cross-sectional views of an exemplary back surface of a device including a monolithic cover structure according to examples of the disclosure. Back surface **1010** of the device can include back plate **1006** and a plurality of cover structures such as cover structure **1007** and cover structure **1017**. Cover structure **1007** and cover structure **1017** can be transparent or translucent (e.g., a

window) and can be disposed over or within one or more of the openings **1001** or cavities.

[0065] Each cover structure **1017** can be optically coupled to a single cavity (e.g., cavity **705** illustrated in FIGS. **7A** and **7C** and cavity **805** illustrated in FIGS. **8A-8B**). Cover structure **1017** can have the same design, features, and/or operation as one or more of cover structure **507** (illustrated in FIG. **5B**), cover structure **607** (illustrated in FIG. **6A**), and cover structure **707** (illustrated in FIG. **7C**). Cover structure **1007** can be a monolithic cover structure having one or more protrusions. For example, cover structure **1007** can have one elongated protrusion, protruding in regions **1011** located in the optical path(s) of the associated optical components and protruding in the region **1013**. Region **1013** can be located between regions **1011** and/or disposed over a portion of the back plate located between a plurality of cavities. In some examples, the height (relative to an outward surface of the back plate) in regions **1011** and region **1013** can be the same (not shown). In some examples, cover structure **1007** can have multiple protrusions, protruding in both regions **1011** and region **1013**, but with different heights. For example, regions **1011** can have the same height, greater than the height of region **1013**. In some examples, each region **1011** can have a different height.

[0066] In some examples, cover structure **1007** can be optically coupled to multiple (e.g., two) cavities. In some examples, cover structure **1007** can be optically coupled to a different type of optical component(s) than the type of optical component(s) that cover structure **1017** can be optically coupled to. For example, cover structures **1017** can be optically coupled to light sensors, whereas cover structure **1007** can be optically coupled to light emitters. In some examples, region **1011** (i.e., region located between the optical path(s) of the associated optical components) may be transparent. In some examples, region **1011** can be opaque and/or include an isolation. In this manner, region **1011** can be configured to create localized pressure, while also optically isolating the optical components located in different cavities.

[0067] The device can include any number of protrusions coupled to the one or more cover structures. In some example, some, but not all, of the cover structures can be associated with a protrusion. FIG. **10C** illustrates a perspective view of an exemplary back surface of a device including a monolithic cover structure that includes protrusions and non-monolithic cover structures that do not include protrusions according to examples of the disclosure. The device can include cover structure **1007** and covers structure **1009**. Cover structure **1007** can include a protrusion to create localized pressure in one or more regions of skin. Cover structure **1009** may not include a protrusion and may not create localized pressure. Cover structure **1009** can be flush (i.e., not protrude) from back plate **1006**. In some examples, cover structure **1009** can be recessed with respect to back plate **1006**. In some examples, the cover structure (e.g., cover structure **1007**) that includes one or more protrusions can be a monolithic cover structure. Additionally or alternatively, the cover structure (e.g., cover structure **1009**) that does not include a protrusion may be a non-monolithic cover structure.

[0068] Examples of the disclosure can include cover structure **1007** optically coupled to a different type of optical component than cover structure **1009** can be optically coupled to. For example, cover structure **1007** can be

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optically coupled to one or more light emitters, whereas cover structure 1009 can be optically coupled to one or more light sensors.

[0069] FIG. 11 illustrates an exemplary block diagram of a computing system comprising one or more protrusions for creating localized pressure according to examples of the disclosure. Computing system 1100 can correspond to any of the computing devices illustrated in FIGS. 1A-1C. Computing system 1100 can include a processor 1110 configured to execute instructions and to carry out operations associated with computing system 1100. For example, using instructions retrieved from memory, processor 1110 can control the reception and manipulation of input and output data between components of computing system 1100. Processor 1110 can be a single-chip processor or can be implemented with multiple components.

[0070] In some examples, processor 1110 together with an operating system can operate to execute computer code and produce and use data. The computer code and data can reside within a program storage block 1102 that can be operatively coupled to processor 1110. Program storage block 1102 can generally provide a place to hold data that is being used by computing system 1100. Program storage block 1102 can be any non-transitory computer-readable storage medium, and can store, for example, history and/or pattern data relating to PPG signals and/or physiological information of the individual measured by one or more light sensors (e.g., light sensor 1104), optically coupled to one or more light emitters (e.g., light emitter 1106, light emitter 1105, and light emitter 1108). In some examples, the system can include one or more protrusions located in the optical path(s) and/or field-of view of the one or more light sensors and/or the one or more light emitters.

[0071] By way of example, program storage block 1102 can include Read-Only Memory (ROM) 1118, Random-Access Memory (RAM) 1122, hard disk drive 1108 and/or the like. The computer code and data could also reside on a removable storage medium and loaded or installed onto the computing system 1100 when needed. Removable storage mediums include, for example, CD-RM, DVD-ROM, Universal Serial Bus (USB), Secure Digital (SD), Compact Flash (CF), Memory Stick, Multi-Media Card (MMC) and a network component.

[0072] Computing system 1100 can also include an input/output (I/O) controller 1112 that can be operatively coupled to processor 1110 or it may be a separate component as shown. I/O controller 1112 can be configured to control interactions with one or more I/O devices. I/O controller 1112 can operate by exchanging data between processor 1110 and the I/O devices that desire to communicate with processor 1110. The I/O devices and I/O controller 1112 can communicate through a data link. The data link can be a one-way link or a two way link. In some cases, I/O devices can be connected to I/O controller 1112 through wireless connections. By way of example, a data link can correspond to PS/2, USB, Firewire, IR, RF, Bluetooth or the like.

[0073] Computing system 1100 can include a display device 1124 that can be operatively coupled to processor 1110. Display device 1124 can be a separate component (peripheral device) or can be integrated with processor 1110 and program storage block 1102 to form a desktop computer (all in one machine), a laptop, handheld or tablet computing device of the like. Display device 1124 can be configured to display a graphical user interface (GUI) including perhaps a

pointer or cursor as well as other information to the individual. By way of example, display device 1124 can be any type of display including a liquid crystal display (LCD), an electroluminescent display (ELD), a field emission display (FED), a light emitting diode display (LED), an organic light emitting diode display (OLED) or the like.

[0074] Display device 1124 can be coupled to display controller 1126 that can be coupled to processor 1110. Processor 1110 can send raw data to display controller 1126, and display controller 1126 can send signals to display device 1124. Data can include voltage levels for a plurality of pixels in display device 1124 to project an image. In some examples, processor 1110 can be configured to process the raw data.

[0075] Computing system 1100 can also include a touch screen 1130 that can be operatively coupled to processor 1110. Touch screen 1130 can be a combination of sensing device 1132 and display device 1124, where the sensing device 1132 can be a transparent panel that is positioned in front of display device 1124 or integrated with display device 1124. In some cases, touch screen 1130 can recognize touches and the position and magnitude of touches on its surface. Touch screen 1130 can report the touches to processor 1110, and processor 1110 can interpret the touches in accordance with its programming. For example, processor 1110 can perform tap and event gesture parsing and can initiate a wake of the device or powering on one or more components in accordance with a particular touch.

[0076] Touch screen 1130 can be coupled to a touch controller 1140 that can acquire data from touch screen 1130 and can supply the acquired data to processor 1110. In some cases, touch controller 1140 can be configured to send raw data to processor 1110, and processor 1110 processes the raw data. For example, processor 1110 can receive data from touch controller 1140 and can determine how to interpret the data. The data can include the coordinates of a touch as well as pressure exerted. In some examples, touch controller 1140 can be configured to process raw data itself. That is, touch controller 1140 can read signals from sensing points 1134 located on sensing device 1132 and turn them into data that the processor 1110 can understand.

[0077] Touch controller 1140 can include one or more microcontrollers such as microcontroller 1142, each of which can monitor one or more sensing points 1134. Microcontroller 1142 can, for example, correspond to an application specific integrated circuit (ASIC), which works with firmware to monitor the signals from sensing device 1132, process the monitored signals, and report this information to processor 1110.

[0078] One or both display controller 1126 and touch controller 1140 can perform filtering and/or conversion processes. Filtering processes can be implemented to reduce a busy data stream to prevent processor 1110 from being overloaded with redundant or non-essential data. The conversion processes can be implemented to adjust the raw data before sending or reporting them to processor 1110.

[0079] In some examples, sensing device 1132 can be based on capacitance. When two electrically conductive members come close to one another without actually touching, their electric fields can interact to form a capacitance. The first electrically conductive member can be one or more of the sensing points 1134, and the second electrically conductive member can be an object 1190 such as a finger. As object 1190 approaches the surface of touch screen 1130,

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a capacitance can form between object 1190 and one or more sensing points 1134 in close proximity to object 1190. By detecting changes in capacitance at each of the sensing points 1134 and noting the position of sensing points 1134, touch controller 1140 can recognize multiple objects, and determine the location, pressure, direction, speed and acceleration of object 1190 as it moves across the touch screen 1130. For example, touch controller 1190 can determine whether the sensed touch is a finger, tap, or an object covering the surface.

[0080] Sensing device 1132 can be based on self-capacitance or mutual capacitance. In self-capacitance, each of the sensing points 1134 can be provided by an individually charged electrode. As object 1190 approaches the surface of the touch screen 1130, the object can capacitively couple to those electrodes in close proximity to object 1190, thereby stealing charge away from the electrodes. The amount of charge in each of the electrodes can be measured by the touch controller 1140 to determine the position of one or more objects when they touch or hover over the touch screen 1130. In mutual capacitance, sensing device 1132 can include a two-layer grid of spatially separated lines or wires, although other configurations are possible. The upper layer can include lines in rows, while the lower layer can include lines in columns (e.g., orthogonal). Sensing points 1134 can be provided at the intersections of the rows and columns. During operation, the rows can be charged, and the charge can capacitively couple from the rows to the columns. As object 1190 approaches the surface of the touch screen 1130, object 1190 can capacitively couple to the rows in close proximity to object 1190, thereby reducing the charge coupling between the rows and columns. The amount of charge in each of the columns can be measured by touch controller 1140 to determine the position of multiple objects when they touch the touch screen 1130.

[0081] A device is disclosed. The device can comprise: one or more optical components; one or more cover structures, each cover structure optically coupled to at least one of the one or more optical components and located on a back surface of the device; a rigid back plate extending from the back surface of the device; and one or more protrusions extending from the rigid back plate, wherein an area of the one or more protrusions is less than an area of the rigid back plate. Additionally or alternatively, in some examples, the one or more protrusions are located between the one or more optical components and one or more edges of the device. Additionally or alternatively, in some examples, the one or more protrusions form a closed ring located around all edges of the device. Additionally or alternatively, in some examples, the device further comprises: one or more openings in a housing of the device, wherein the one or more optical components and the one or more cover structures are located at least partially in the one or more openings, and the one or more protrusions at least partially surround the one or more openings. Additionally or alternatively, in some examples, the one or more protrusions are configured to create a localized pressure to one or more regions of a skin of an individual, and the one or more regions are located in an optical path of the one or more optical components. Additionally or alternatively, in some examples, the one or more protrusions are separate and distinct structures adhered to the rigid back plate. Additionally or alternatively, in some examples, the device further comprises: one or more recesses surrounded by the one or more protrusions; and one

or more cavities located in a housing of the device, wherein the one or more optical components are located in the one or more cavities, and each recess is associated with at least one of the one or more cavities. Additionally or alternatively, in some examples, each cavity is associated with at least two recesses, the at least two recesses having different depths from a surface of the rigid back plate. Additionally or alternatively, in some examples, each cavity is associated with one of the one or more cover structures, and the one or more cover structures are recessed with respect to a surface of the rigid back plate. Additionally or alternatively, in some examples, the device further comprises: one or more second cover structures optically coupled to one or more light sensors, the one or more light sensors included in the one or more optical components, wherein the one or more cover structures include the one or more protrusions and are optically coupled to one or more light emitters, the light emitters included in the one or more optical components. Additionally or alternatively, in some examples, the rigid back plate has a curved surface. Additionally or alternatively, in some examples, the rigid back plate is separate and distinct from the one or more cover structures.

[0082] A device is disclosed. The device can comprise: one or more optical components; a rigid back plate located on a back surface of the device; and one or more cover structures, each cover structure optically coupled to at least one of the one or more optical components and located on the back surface, wherein each cover structure is at least partially transparent and protrudes from the rigid back plate. Additionally or alternatively, in some examples, at least one of the one or more cover structures includes a first protrusion having a first protrusion height from a surface of the rigid back plate and a second protrusion having a second protrusion height from the surface of the rigid back plate, the second protrusion height greater than the first protrusion height. Additionally or alternatively, in some examples, the rigid back plate has a third protrusion height from the back surface of the device, wherein the third protrusion height is less than a height of the first protrusion from the back surface of the device. Additionally or alternatively, in some examples, the device further comprises: one or more Fresnel lenses optically coupled to the one or more cover structures. Additionally or alternatively, in some examples, at least one of the one or more Fresnel lenses includes multiple optical centers. Additionally or alternatively, in some examples, the one or more cover structures include an isolation configured to optically isolate light rays from optical components located on different sides of a given cover structure. Additionally or alternatively, in some examples, at least one cover structure is a monolithic cover structure optically coupled to a plurality of cavities and disposed over a portion of the rigid back plate located between the plurality of cavities. Additionally or alternatively, in some examples, the monolithic cover structure includes a plurality of regions, each region disposed over one of the plurality of cavities, wherein a height of each region is greater than a height of the cover structure disposed over the portion of the rigid back plate. Additionally or alternatively, in some examples, the one or more cover structures are integrated into the rigid back plate.

[0083] A method for determining one or more physiological signals of an individual is disclosed. The method can comprise: emitting light from one or more light emitters; allowing the emitted light to pass through one or more first cover structures; receiving at least a portion of the emitted

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light using one or more light sensors; creating a first localized pressure at one or more first regions of a skin of the individual; allowing the at least the portion of the emitted light to pass through one or more second cover structures; generating one or more signals indicative of the received light; and determining the one or more physiological signals of the individual from the one or more signals. Additionally or alternatively, in some examples, the localized pressure is created at multiple spatially separated first regions of the skin of the individual. Additionally or alternatively, in some examples, the method further comprises: creating a second localized pressure at one or more second regions of the skin of the individual, the second localized pressure greater than the first localized pressure. Additionally or alternatively, in some examples, the first localized pressure is created by the one or more first cover structures.

[0084] A method for determining one or more physiological signals of an individual is disclosed. The method can comprise: emitting light from one or more light emitters located on a first side of a cover structure; optically isolating the emitted light from a second side of the cover structure; allowing the emitted light to pass through the first side of the cover structure; allowing at least a portion of the emitted light to pass through the second side of the cover structure; optically isolating the at least the portion of the emitted light from the second side of the cover structure; receiving the at least the portion of the emitted light using one or more light sensors located on the second side of the cover structure; generating one or more signals indicative of the received light; and determining the one or more physiological signals of the individual from the one or more signals. Additionally or alternatively, in some examples, the method further comprises: collimating the emitted light using one or more Fresnel lenses.

[0085] Although examples have been fully described with reference to the accompanying drawings, it is to be noted that various changes and modifications will become apparent to those skilled in the art. Such changes and modifications are to be understood as being included within the scope of the various examples as defined by the appended claims.

1. A device comprising:

one or more optical components;

one or more cover structures, each cover structure optically coupled to at least one of the one or more optical components and located on a back surface of the device;

a rigid back plate extending from the back surface of the device; and

one or more protrusions extending from the rigid back plate, wherein an area of the one or more protrusions is less than an area of the rigid back plate.

2. The device of claim 1, wherein the one or more protrusions are located between the one or more optical components and one or more edges of the device.

3. The device of claim 2, wherein the one or more protrusions form a closed ring located around all edges of the device.

4. The device of claim 1, further comprising:

one or more openings in a housing of the device, wherein the one or more optical components and the one or more cover structures are located at least partially in the one or more openings, and the one or more protrusions at least partially surround the one or more openings.

5. The device of claim 1, wherein the one or more protrusions are configured to create a localized pressure to one or more regions of a skin of an individual, and the one or more regions are located in an optical path of the one or more optical components.

6. The device of claim 1, further comprising:

one or more recesses surrounded by the one or more protrusions; and

one or more cavities located in a housing of the device, wherein the one or more optical components are located in the one or more cavities, and each recess is associated with at least one of the one or more cavities.

7. The device of claim 6, wherein each cavity is associated with at least two recesses, the at least two recesses having different depths from a surface of the rigid back plate.

8. The device of claim 6, wherein each cavity is associated with one of the one or more cover structures, and the one or more cover structures are recessed with respect to a surface of the rigid back plate.

9. The device of claim 1, further comprising:

one or more second cover structures optically coupled to one or more light sensors, the one or more light sensors included in the one or more optical components, wherein the one or more cover structures include the one or more protrusions and are optically coupled to one or more light emitters, the light emitters included in the one or more optical components.

10. A device comprising:

one or more optical components;

a rigid back plate located on a back surface of the device; and

one or more cover structures, each cover structure optically coupled to at least one of the one or more optical components and located on the back surface, wherein each cover structure is at least partially transparent and protrudes from the rigid back plate.

11. The device of claim 10, wherein at least one of the one or more cover structures includes a first protrusion having a first protrusion height from a surface of the rigid back plate and a second protrusion having a second protrusion height from the surface of the rigid back plate, the second protrusion height greater than the first protrusion height.

12. The device of claim 11, wherein the rigid back plate has a third protrusion height from the back surface of the device, wherein the third protrusion height is less than a height of the first protrusion from the back surface of the device.

13. The device of claim 10, further comprising:

one or more Fresnel lenses optically coupled to the one or more cover structures.

14. The device of claim 10, wherein at least one of the one or more Fresnel lenses includes multiple optical centers.

15. The device of claim 10, wherein at least one cover structure is a monolithic cover structure optically coupled to a plurality of cavities and disposed over a portion of the rigid back plate located between the plurality of cavities.

16. The device of claim 15, wherein the monolithic cover structure includes a plurality of regions, each region disposed over one of the plurality of cavities, wherein a height of each region is greater than a height of the cover structure disposed over the portion of the rigid back plate.

17. A method for determining one or more physiological signals of an individual, the method comprising:

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emitting light from one or more light emitters;
allowing the emitted light to pass through one or more first cover structures;
receiving at least a portion of the emitted light using one or more light sensors;
creating a first localized pressure at one or more first regions of a skin of the individual;
allowing the at least the portion of the emitted light to pass through one or more second cover structures;
generating one or more signals indicative of the received light; and
determining the one or more physiological signals of the individual from the one or more signals.

18. The method of claim 17, further comprising:

creating a second localized pressure at one or more second regions of the skin of the individual, the second localized pressure greater than the first localized pressure.

19. A method for determining one or more physiological signals of an individual, the method comprising:

emitting light from one or more light emitters located on a first side of a cover structure;
optically isolating the emitted light from a second side of the cover structure;
allowing the emitted light to pass through the first side of the cover structure;
allowing at least a portion of the emitted light to pass through the second side of the cover structure;
optically isolating the at least the portion of the emitted light from the second side of the cover structure;
receiving the at least the portion of the emitted light using one or more light sensors located on the second side of the cover structure;
generating one or more signals indicative of the received light; and
determining the one or more physiological signals of the individual from the one or more signals.

20. The method of claim 19, further comprising:
collimating the emitted light using one or more Fresnel lenses.

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PRESS RELEASE

April 9, 2015

Apple Watch In-Store Preview & Online Pre-Order Begin Friday

Available for Purchase Online April 24

CUPERTINO, California—April 9, 2015—Apple Watch™, Apple's most personal device yet, will be available for preview and pre-order on Friday, April 10. Customers in Australia, Canada, China, France, Germany, Hong Kong, Japan, the UK and the US can try on and experience Apple Watch at their local Apple Store® or at Galeries Lafayette in Paris, Isetan in Tokyo, Selfridges in London, and select Apple Authorized Resellers in Japan and China. Customers can pre-order their Apple Watch through the [Apple Online Store](#) (www.apple.com) beginning April 10 at 12:01 a.m. PDT for delivery beginning April 24.

"We are excited to welcome customers tomorrow and introduce them to Apple Watch, our most personal device yet. Based on the tremendous interest from people visiting our stores, as well as the number of customers who have gone to the Apple Online Store to mark their favorite Apple Watch ahead of availability, we expect that strong customer demand will exceed our supply at launch," said Angela Ahrendts, Apple's senior vice president of Retail and Online Stores. "To provide the best experience and selection to as many customers as we can, we will be taking orders for Apple Watch exclusively online during the initial launch period."

Customers interested in learning more about Apple Watch can visit their local Apple Store for a personalized session with a Specialist to try on, fit and size their band, and explore the amazing features of Apple Watch. Customers who want to try on an Apple Watch are

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encouraged to make an appointment by going to www.apple.com.

Starting Friday, customers can try on Apple Watch, Apple Watch Sport or Apple Watch Edition* to find the model with the size, finish and band to best fit their personal preference and style. Everyone visiting an Apple Store will be able to view all three collections and get hands on with Apple Watch Demo to browse and edit different watch faces, and learn about Apple Watch's health and fitness features, Digital Touch, Siri®, Apple Pay™** and more.

Pre-orders begin April 10 at 12:01 a.m. PDT through the Apple Online Store, the Apple Store app for iPhone® and iPad®, and select Apple Authorized Resellers in China and Japan. Customers who pre-order their Apple Watch can have it shipped for delivery beginning April 24. All Apple Watch customers will be offered Personal Setup, online or in-store, to pair their Apple Watch with their iPhone. New owners will also learn how to personalize Apple Watch by selecting a watch face, deciding which notifications to receive, setting up the Activity app, and receive an introduction to Apple Pay** and the Apple Watch App Store™.

Beginning April 24, Apple Watch will also be available at boutiques in major cities including colette in Paris, Dover Street Market in London and Tokyo, Maxfield in Los Angeles and The Corner in Berlin, and select Apple Authorized Resellers in China and Japan.

Apple Watch is an incredibly accurate timepiece, an intimate and immediate communication device and a groundbreaking health and fitness companion. Highly customizable for personal expression, Apple Watch also brings an entirely new way to receive information at a glance and interact with the world through third-party app experiences designed specifically for the wrist.

Apple Watch introduces revolutionary technologies including the Digital Crown™, an innovative way to scroll, zoom and navigate fluidly without obstructing the display. The Retina® display with Force Touch on Apple Watch senses the difference between a tap and a press, providing a new way to quickly and easily access relevant controls. The all-new Taptic Engine™ discreetly delivers a gentle tap on your wrist whenever you receive a notification or message.

Pricing & Availability

Apple Watch is available in three collections, Apple Watch Sport, priced at \$349 (US) and \$399 (US); Apple Watch, available from \$549 (US) to \$1,099 (US); and Apple Watch Edition, crafted from custom rose or yellow 18-karat gold alloys, with prices starting at \$10,000 (US).

More information about where to buy Apple Watch is available

at locate.apple.com.

Apple Watch requires iPhone 5, iPhone 5c, iPhone 5s, iPhone 6 or iPhone 6 Plus running iOS 8.2 or later.

*Apple Watch Edition is available for try-on at select stores.

**Apple Pay is only available in the US and through participating banks.

Apple designs Macs, the best personal computers in the world, along with OS X, iLife, iWork and professional software. Apple leads the digital music revolution with its iPods and iTunes online store. Apple has reinvented the mobile phone with its revolutionary iPhone and App Store, and is defining the future of mobile media and computing devices with iPad.

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Newsroom Apple Watch In-Store Preview & Online Pre-Order Begin Friday

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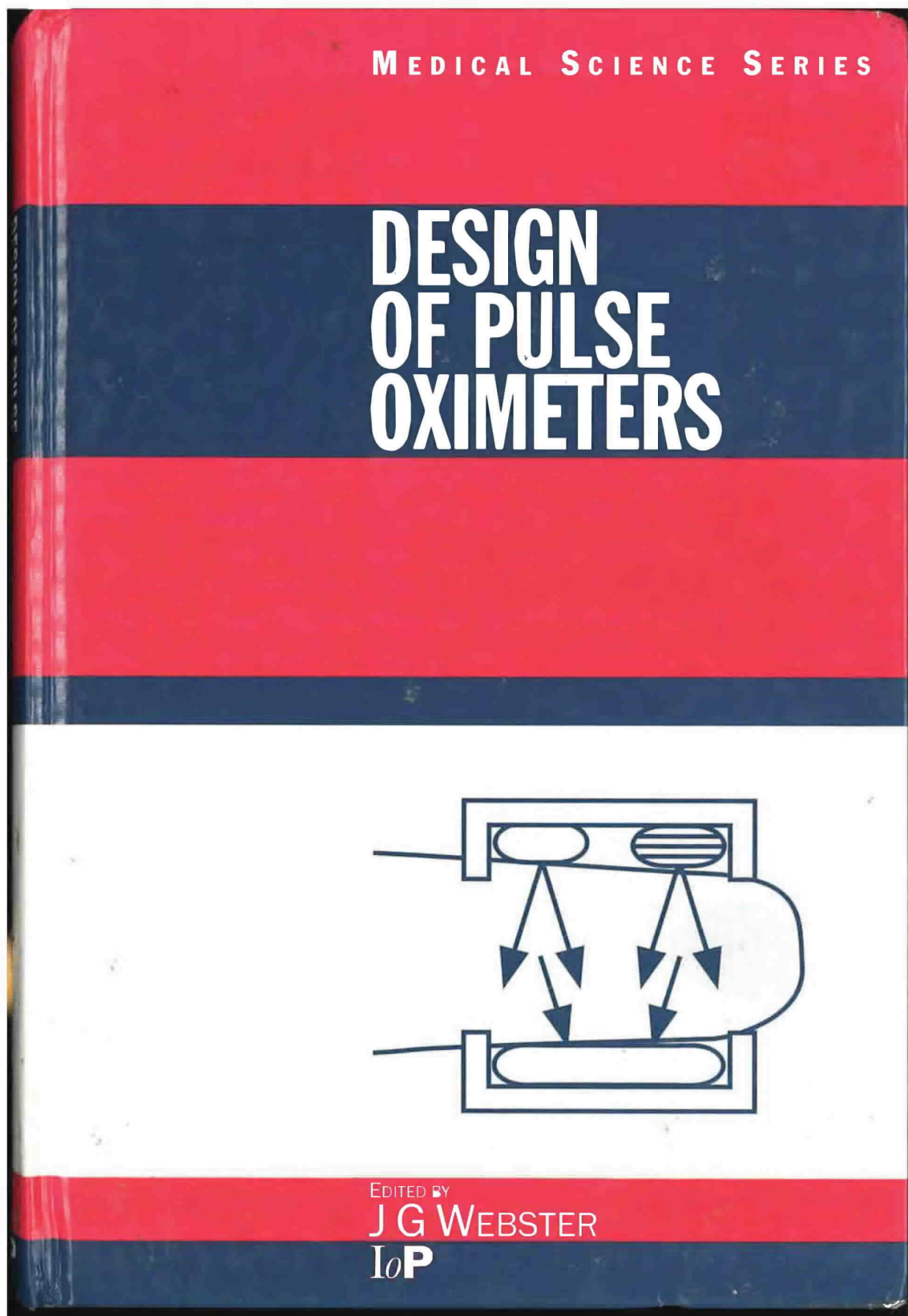
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British Library Cataloguing-in-Publication Data

A catalogue record for this book is available from the British Library.

ISBN 0 7503 0467 7

Library of Congress Cataloging-in-Publication Data are available

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Published by Institute of Physics Publishing, wholly owned by The Institute of Physics, London

Institute of Physics Publishing, Dirac House, Temple Back, Bristol BS1 6BE, UK

US Editorial Office: Institute of Physics Publishing, The Public Ledger Building, Suite 1035, 150 South Independence Mall West, Philadelphia, PA 19106, USA

Prepared by the Editor using Microsoft Word 6

Printed in Great Britain by J W Arrowsmith Ltd, Bristol

PREFACE

Pulse oximetry was introduced in 1983 as a noninvasive method for monitoring the arterial oxygen saturation of a patient's blood. Recognized worldwide as the standard of care in anesthesiology, it is widely used in intensive care, operating rooms, emergency, patient transport, general wards, birth and delivery, neonatal care, sleep laboratories, home care and in veterinary medicine. It provides early information on problems in the delivery of oxygen to the tissue. Those problems may arise because of improper gas mixtures, blocked hoses or airways, inadequate ventilation, diffusion, or circulation, etc. More than 35 companies manufacture and distribute the more than 300 000 pulse oximeters presently in use in the USA.

This book emphasizes the design of pulse oximeters. It details both the hardware and software required to fabricate a pulse oximeter as well as the equations, methods, and software required for effective functioning. Additionally, it details the testing methods and the resulting accuracy. The book should be of interest to biomedical engineers, medical physicists, and health care providers who want to know the technical workings of their measuring instruments.

Chapter 1 reviews the methods of transport of oxygen to the tissue by ventilation, perfusion to the blood, binding to hemoglobin in the red blood cells, and transport through the blood circulation. Chapter 2 describes the problems and diseases that can occur in oxygen transport, which motivate us to measure oxygenation. In chapter 3, we review the many ways oxygenation has been measured in the past, the CO-oximeter used as the gold standard, and provide an introduction to the pulse oximeter.

Chapter 4 begins with Beer's law for the absorption of light by hemoglobin and oxyhemoglobin, and develops the equations required for converting measured light transmission through the tissue to display the hemoglobin oxygen saturation. The light-emitting diodes, which alternately emit red light at 660 nm and infrared light at 940 nm and require precise wavelength control, are described in chapter 5. Chapter 6 covers the variety of light sensors, with emphasis on the single photodiode typically used.

Chapter 7 details the design of reusable and disposable probes and their flexible cables. The probes can transmit light through either the finger or ear, or use reflected light from the scalp or other skin surface. Chapter 8 covers the hardware, with block diagrams showing how red and infrared signals are amplified to yield the ratio of pulse-added red absorbance to the pulse-added infrared absorbance. These signals are used to control light-emitting diode levels and the ratio is used to calculate oxygen saturation. The flow charts and

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algorithms to perform oxygen saturation calculations are given in chapter 9, with worked out examples. Synchronization with the electrocardiogram improves accuracy during patient movement.

Chapter 10 describes ways to test performance of pulse oximeters: the technician's finger, electronic simulators, *in vitro* test systems, and optoelectronic simulators. In chapter 11, we find the resulting accuracies and descriptions of the inaccuracies caused by alternative forms of hemoglobin, optical and electrical interference, colored nail polish, etc. Chapter 12 describes the interface between the pulse oximeter, the operator, and the external world. Chapter 13 covers the many applications for pulse oximetry in intensive care, operating rooms, emergency, patient transport, general wards, birth and delivery, neonatal care, sleep laboratories, home care, and in veterinary medicine.

A glossary provides definitions of terms from both the medical and the engineering world. We also provide instructional objectives as a means of provoking further thought toward learning the information. We gleaned much of the design information from operator's manuals and from patents; periodical literature provided more general information. Rather than giving an exhaustive list of references, we have included review articles and books that can serve as an entry into further study. All contributors are from the Department of Electrical and Computer Engineering at the University of Wisconsin, Madison, WI, USA, and worked as a team to write this book. We would welcome suggestions for improvement of subsequent printings and editions.

John G. Webster

Department of Electrical and Computer Engineering
University of Wisconsin-Madison
Madison WI, USA
August 1997

CHAPTER 2

MOTIVATION OF PULSE OXIMETRY

Daniel J Sebald

Pulse oximeters have been commercially available for a little more than the last decade and have seen a tremendous growth in popularity becoming a quasi-standard, if not standard, monitoring device in hospital critical care units and surgical theaters. The instrument transcutaneously estimates oxygen saturation of arterial blood and provides vital information about the cardiorespiratory function of the patient. Pulse oximetry provides an empirical measure of arterial saturation. However, with state-of-the-art instrumentation and proper initial calibration, the correlation between the pulse oximeter measurement, S_pO_2 , and arterial blood's actual oxygen saturation, S_aO_2 , is adequate—generally less than 3% discrepancy provided S_aO_2 is above 70% (Severinghaus and Kelleher 1992)—for medical applications where detecting hypoxemia is essential. Quick acceptance of pulse oximetry as a monitoring device for surgery, recovery, critical care and research has shown that for determining hypoxemia any reasonably small loss in accuracy that may be attributed to measuring arterial oxygen saturation transcutaneously is outweighed by the advantages of noninvasiveness and continuous, immediate availability of data. In applications where accuracy is paramount, such as in detecting hyperoxia, the use of pulse oximetry is not so clear and remains to be decided in the medical community. However, mounting evidence suggests that the pulse oximeter is not very useful in these situations. Nonetheless, the importance of detecting hypoxemia, where pulse oximetry is best suited, is so great that the instrument plays a critical role in medicine despite its limitations.

2.1 PULSE OXIMETER PRINCIPLES

A pulse oximeter shines light of two wavelengths through a tissue bed such as the finger or earlobe and measures the transmitted light signal. The device operates on the following principles:

1. The light absorbance of oxygenated hemoglobin and deoxygenated hemoglobin at the two wavelengths is different. To be more precise, the set of associated extinction coefficients for the absorption of light for these wavelengths is linearly independent with great enough variation for adequate sensitivity but not so large that the blood appears opaque to either of the

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light sources. This model assumes that only oxygenated and deoxygenated hemoglobin are present in the blood.

2. The pulsatile nature of arterial blood results in a waveform in the transmitted signal that allows the absorbance effects of arterial blood to be identified from those of nonpulsatile venous blood and other body tissue. By using a quotient of the two effects at different wavelengths it is possible to obtain a measure requiring no absolute calibration with respect to overall tissue absorbance. This is a clear advantage of pulse oximeters over previous types of oximeters.
3. With adequate light, scattering in blood and tissue will illuminate sufficient arterial blood, allowing reliable detection of the pulsatile signal. The scattering effect necessitates empirical calibration of the pulse oximeter. On the other hand, this effect allows a transmittance path around bone in the finger.

The principles above, associated issues and design and application of pulse oximeters comprise the better part of this text. The remainder of this chapter concentrates on the role and importance of pulse oximetry and limitations of the device.

2.2 S_pO_2 AS MONITOR OF HEMOGLOBIN OXYGENATION

Lack of oxygen can quickly lead to irreversible damage to cell tissue having a high metabolic rate, the heart and central nervous system being two examples. Although the human body is surprisingly robust in many ways, the physiological process of sustaining proper cell function via oxygen transport is a delicate and complex control system; one which if altered too significantly could become unstable and insufficient for meeting oxygen tissue demands. To emphasize the importance of proper tissue oxygenation, Table 2.1 lists survival times for different organ beds after the onset of anoxia, or cardiac arrest. Hence, it is important to safeguard against pathological conditions that might lead to improper tissue oxygenation.

Table 2.1 Organ robustness to anoxia (cardiac arrest), a consequence of metabolic rate and cellular oxygen stores. *Survival* time is the time before cellular damage occurs after total loss of oxygen delivery. *Revival* time is the time before function of the organ can no longer be restored. Revival times are generally four times longer than survival times in most organs except the brain, which has a revival time five times longer than its survival time (adapted from Nunn 1987).

Organ	Survival time after onset of anoxia
Cerebral cortex	less than 1 min
Heart	5 min
Liver and kidney	10 min
Skeletal muscle	2 h

2.2.1 Comprehensive approach

Arterial saturation, the variable which pulse oximetry is intended to measure, is just one of several variables a physician will consider when assessing the condition of a patient's cardiopulmonary system. In this regard, the clinician will address the fundamental issue of whether or not body tissue is being properly oxygenated (Vender 1992). This requires a comprehensive approach whereby arterial saturation plays a certain role. It is an extremely important one, but physicians typically do not use S_aO_2 as a sole monitor for pathological oxygenation conditions.

2.2.2 Arterial oxygen saturation

Arterial oxygen saturation pertains to blood in the arteries and arterioles throughout the body. This blood is of the same saturation throughout the arterial system. It is at the capillary level that saturation levels change. In a healthy adult, the normal operating range for S_aO_2 is greater than 90%, which corresponds to an arterial partial pressure, P_aO_2 , of 60 to 100 mmHg (Ahrens and Rutherford 1993).

Owing to the complexity of the oxygenation process, it is difficult to address the wealth of uses for arterial saturation in critical care settings, operating rooms, and research laboratories. Physicians are interested in knowing S_aO_2 for a variety of reasons. Sometimes it is for quantitative assessment. Sometimes it serves as an important variable for safeguarding against, although it is not a direct indication of the dangerous condition of low cellular oxygenation. Table 2.2 gives several respiratory problems that might cause low S_aO_2 , but this is by no means a complete list.

Table 2.2 Respiratory problems that might result in low S_aO_2 (adapted from Des Jardins 1990, Cherniack and Cherniack 1983, and Selecky 1982).

Respiratory problem	Example disease or possible source of problem
Poor lung compliance	Pneumonia, ARDS, fibrosis, emphysema
Increased airway resistance	Asthma, chronic bronchitis, cystic fibrosis
Low pulmonary diffusion capacity	Emphysema, pulmonary alveolar proteinosis
Airway obstruction	Choking, secretions from intubation, obstructive sleep apnea
Ventilatory muscle weakness	Lead poisoning, trauma to phrenic nerve
Increased true venous admixture	Congenital heart disease
Low inspired partial pressure of oxygen	Anesthesia equipment failure, high altitude
Hypoventilation	Acid-base imbalance

2.2.3 Hypoxia and hypoxemia

Hypoxia means lower than normal tissue oxygenation. *Hypoxemia* means lower than normal blood oxygenation. These are two quite different concepts. Hypoxia refers to the critically dangerous condition where cell function is in jeopardy. Table 2.3 shows different categories of hypoxia. The first category, hypoxic hypoxia, is a consequence of low arterial saturation. Hence, hypoxemia is a dangerous condition. However, it is not necessary that hypoxia exist under conditions of hypoxemia. Likewise, as table 2.3 suggests, hypoxia may occur

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when there is no evidence of hypoxemia. Therefore, a clinician carefully interprets results from monitoring blood oxygen content because S_aO_2 and, consequently, S_pO_2 provide *only* a measure of hypoxemia, *not* a measure of hypoxia.

Table 2.3 Different types of hypoxia (adapted from Bredle 1989, and Des Jardins 1990).

Type of hypoxia	Description
Hypoxic hypoxia	Arterial blood is poorly oxygenated due to low $F_{I}O_2$ or respiratory disease
Anemic hypoxia	Blood cannot transport adequate oxygen due to hemoglobin abnormalities
Circulatory hypoxia	Cardiac output is low or blood perfusion is inadequate
Histotoxic hypoxia	The tissue is incapable of using otherwise sufficient supplies of oxygen

2.2.4 Role of SpO_2 in avoiding hypoxia

Although monitoring blood oxygen saturation provides only clues to the oxygenation of cells, there is one variable which provides better evidence of hypoxia. That is lactate content of the blood. Energy utilization may take place in an anaerobic environment, and the byproduct of such a process is lactate. However, the anaerobic process is inefficient for generating energy, and cells cannot operate for long in this situation. The presence of lactate is not a problem initially because it may be broken down if oxygen stores are replenished soon enough (Ahrens and Rutherford 1993). Lactic acidosis occurs if this is not the case. This, in turn, affects the pH of blood which influences the cardiac and pulmonary control systems. However, if cardiac output and respiratory rate cannot increase the delivered oxygen, a dangerous situation results.

Although lactic acidosis may be a better indicator of hypoxia than arterial blood saturation, the problem is that lactic acidosis is an after-the-fact occurrence. As pointed out by Vender (1992), cell damage is likely occurring upon noting an increase in lactate. Herein lies the true value of blood saturation measurement. If monitored appropriately, it can help signal dangerous pathological conditions before cell damage occurs. However, as alluded to earlier S_pO_2 (i.e., S_aO_2) alone is not as helpful as when supplemented with measures of cardiac output, functional hemoglobin, blood pressure, heart rate, respiratory rate, urine output, patient comfort and a variety of other variables.

2.2.4.1 Anesthesiology. Tissue oxygenation and, consequently, blood saturation are of extreme importance to the anesthesiologist because the patient's cardiopulmonary system is placed in a state where it can no longer meet oxygen demands on its own. In a sense, the anesthetist becomes the controller for the patient's respiratory system, and S_pO_2 provides one of the better feedback variables. As a monitoring device to assist the anesthetist, pulse oximetry has literally revolutionized the field of anesthesiology because of its noninvasive nature, fast response and affordability (Fairley 1989). Note that the transition to pulse oximetry was not without controversy (Payne and Severinghaus 1985). Cyanosis, heart rate and blood pressure were generally what was available to the anesthesiologist for detecting hypoxia before the advent of pulse oximetry (Fairley 1989). Similar to lactate, all these variables are after-the-fact

occurrences of hypoxia. Again, S_pO_2 does not give direct indication of hypoxia, which has its drawbacks, but it can be an early warning of its occurrence.

The most frequent use of pulse oximeters is by anesthesiologists during surgery and for about an hour afterwards in the recovery room. Anesthesiologists administer narcotics to the patient to suppress the central nervous system. This stops the patient's desire to breathe. In addition, they administer muscle relaxants, which stops the ability to breathe and permits airways to collapse. Thus, it is necessary to restore breathing through intubation and artificial respiration. Anesthesiologists can monitor several variables, but most have limitations of late or unreliable response to an oxygenation problem.

Blood pressure declines long after oxygen declines, and the ECG indicates problems even later than blood pressure. An esophageal stethoscope indicates within one beat when the heart has stopped, but this is also long after oxygen has declined. The anesthesiologist can check for cyanosis. Again, this occurs long after oxygen has declined. Blood gas samples give an accurate measurement of oxygen, carbon dioxide, and pH but take about 5 min to process.

Pulse oximeters solved the problem of delay by continuously and noninvasively monitoring arterial oxygen saturation. Recall that adequate arterial saturation does not imply proper oxygenation. Furthermore, there is a delay between noting a drop in S_pO_2 and its cause. However, of the monitored variables, S_pO_2 is currently the best indication that an oxygenation problem exists or is about to occur, and it does so noninvasively.

The pulse oximeter probe is usually applied to the finger, since the body will decrease blood flow to the finger before more vital organs. It is more difficult to reliably secure probes to the ear, nose, and forehead. An arterial oxygen saturation drop from 98 to 96% alerts the anesthesiologist that something is going on. If the oxygen saturation drops to 90%, the default alarm sounds, which indicates that a serious problem may be at hand.

Continuously monitoring S_pO_2 catches several equipment malfunctions and improper placement of tracheal tubes, but naturally it does not identify the problem (Payne and Severinghaus 1985). The fact that S_pO_2 does not identify the source of the problem should not be viewed as a drawback to the pulse oximeter. Instead, this has implications in how to view pulse oximetry as a monitored variable. Fairley (1989) has figuratively stated the role of pulse oximetry in anesthesiology (Original metaphor attributed to Tremper and Barker (1989)):

It was not until effective pulse oximetry became commercially available, for the first time, that large numbers of anesthesiologists could continuously monitor their patients' arterial oxygen levels. It is very important to recognize the nature of this monitoring. Since virtually every anesthetized patient breathes an oxygen enriched mixture, desaturation only occurs when there is a substantial increase in the difference between the (perceived) inspired oxygen tension and that in the arterial blood. Metaphorically, as the blindfolded anesthetist walks unknowingly towards the cliff of hypoxia—whether due to problems of inspired gas, equipment failure, underventilation, or abnormal pulmonary shunting—the protective hand of the pulse oximeter sentry stops him from falling over the edge. The oximeter will not tell him why he has been proceeding in that direction, or the direction back! On the other hand, should he start falling, the sentry functions on the vertical part of the dissociation curve and becomes an extremely

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sensitive (if not always accurate) indicator of progress during the drop. Interestingly, it is highly probable that many fewer blood gas samples are being drawn during anesthesia now that pulse oximeters are so universally available. Our detailed insight into our patients' pulmonary oxygen exchange is less than with P_aO_2 measurement but, because of the continuously available sentry, we believe our patients are safer. A prospective study to prove that important point with certainty may never be performed but, already, opinion seems overwhelmingly in favor of that belief.

Pulse oximetry has become a *de facto* standard for the American Society of Anesthesiologists (Eichhorn 1993). This means that, as alluded to in Fairley's description, although definitive statistical proof of the benefit of pulse oximetry may never be shown because of the rarity of complications due to anesthesiology in the operating theater, a large majority of those who use the device feel that it helps to reduce complications.

2.2.4.2 Postoperative and critical care. Pulse oximetry has proven very important to postoperative recovery because the patient's pulmonary control may still be compromised from the effects of anesthesia. For example, a randomized study by Lampe *et al.* (1990) found that of 141 patients having carotid endarterectomy 63% had episodes of S_pO_2 less than 90% and 21% had episodes of S_pO_2 less than 86% during the postoperative period. Similar studies also show large numbers of desaturation episodes, although variation in the data does exist (Severinghaus and Kelleher 1992).

The role of pulse oximetry in intensive and critical care units is similar to that for anesthesiology, although the patient's respiratory system may not be suppressed by narcotics and muscle relaxants. The instrument still acts as the sentry warning of desaturation from a variety of conditions, some of which were listed in table 2.2. In this setting, alarms and temporal records are very useful when constant surveillance of the patient is not possible.

2.2.4.3 Exams and research studies. The pulse oximeter is an excellent device for medical research studies such as sleep apnea and hypoxic ventilatory response (Severinghaus and Kelleher 1992). Medical exams such as stress tests also benefit from the noninvasive, continuous nature of pulse oximetry. In such cases, S_pO_2 may be used to catch hypoxemic events and also correlated with other variables to glean information about the patient's general health.

2.2.5 Photoplethysmography

Most pulse oximeters on the market feature a photoplethysmograph. The signal for the photoplethysmograph is derived from the same waveforms used to calculate S_pO_2 . The photoplethysmograph may be used in a clinical setting in the same manner as a plethysmograph. However, the accuracy of the photoplethysmograph suffers from motion artifacts, and the patient must have adequate blood perfusion near placement of the pulse oximeter probe. Just as with the conventional plethysmogram, signal processing can derive heart rate from the photoplethysmogram waveform. Hence, most pulse oximeters also display heart rate. Similar to computing S_pO_2 , temporal low-pass filtering abates the effect of motion artifacts on heart rate estimation.

2.2.6 Hyperoxia

Hyperoxia is the condition where blood in the system contains more than the normal amount of oxygen. Determining excessive levels of oxygen is important in many situations because of the toxic nature of oxygen radicals. Studies suggest that pulse oximetry is not useful for this type of application. For example, the role of S_aO_2 for determining retinopathy of prematurity in neonates is not quite clear, and furthermore the 2 to 3% inaccuracy of S_pO_2 for estimating S_aO_2 adds to this uncertainty (Severinghaus and Kelleher 1992).

2.3 LIMITATIONS

2.3.1 Instrument and operation limitations

Many of the limitations to pulse oximetry will come to light throughout the remainder of this text. However, table 2.4 summarizes some limitations given by Severinghaus and Kelleher (1992). These are described in detail in the original source.

Table 2.4 Limitations to pulse oximetry and its application in a clinical setting. Adapted from Severinghaus and Kelleher (1992).

Pulse oximetry limitations
Instrument incidence of failure
Low signal-to-noise ratio
Light shunting and poorly applied probe
Vasoconstrictors
Low-perfusion limits
Motion artifacts
Abnormal pulses
Ventilator-induced and venous pulse interference
Response times
Ambient light
Electrosurgery
Interference of MRI
Site selection for probe placement
Skin pigments, dyes, and nail polish
Dysfunctional hemoglobins
Burns and other dangers
False alarms and false nonalarms

2.3.2 Limitations in S_aO_2

Often in anesthesiology medical literature, articles regarding a limitation of pulse oximetry appear in which, if read more closely, what is actually meant is a limitation in monitoring arterial oxygen saturation, e.g., Hutton and Clutton-Brock (1993), and Mak (1993). Authors of such articles point out this fact. It is interesting how measuring S_pO_2 has become so associated with measuring S_aO_2 .

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Nonetheless, it follows that any limitations associated with S_aO_2 as a monitored variable are also associated with S_pO_2 .

There are some caveats to using S_aO_2 to assess the condition of pulmonary function. It is difficult to regard any monitoring technique as foolproof, as there are usually misleading combinations of conditions that will result in the monitored variable appearing fine when, in fact, a potentially dangerous condition could exist for the patient. For example, Hutton and Clutton-Brock (1993) and Mak (1993) point out that pulse oximetry (i.e., S_aO_2) is a poor measure of hypoventilation when inspired oxygen concentration is high. It is in situations like this that a comprehensive approach to oxygenation assessment using other monitored variables is imperative.

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INSTRUCTIONAL OBJECTIVES

- 2.1 State the fundamental question a clinician should ask when assessing the cardiopulmonary condition of a critically ill patient.
- 2.2 Give the normal values for S_aO_2 and P_aO_2 in the healthy adult.
- 2.3 State the difference between hypoxia, hypoxemia and hyperoxia.
- 2.4 Give several common problems that result in hypoxemia.
- 2.5 Describe the role of lactate as an indicator of improper oxygen transport.
- 2.6 Describe the role of S_pO_2 as an indicator of improper oxygen transport.
- 2.7 List several physiologic variables that may be used in conjunction with S_aO_2 for assessing a patient's cardiopulmonary condition.
- 2.8 Describe why pulse oximetry data are of importance to anesthesiology.
- 2.9 State how useful pulse oximetry is in detecting hyperoxia.
- 2.10 List several limitations to pulse oximetry.

CHAPTER 3

BLOOD OXYGEN MEASUREMENT

James Farmer

Oximetry is a general term that refers to the optical measurement of oxyhemoglobin saturation in the blood (Peterson 1986). Pulse oximetry is only one of those technologies. There are other methods of measuring oxygen content of the blood as well. Gradwohl (1948) describes two colorimetric methods of estimating the HbO_2 of the blood by direct comparison to a color chart. The Dare method used a thin layer of undiluted blood which was matched against a standard series of colored disks. The Tallqvist method used a drop of undiluted blood placed on absorbent paper. The absorbent paper was compared with a graded scale of colored blocks printed on paper. The Tallqvist method was reported to be inaccurate and not recommended. No information on the reliability of the Dare method was given.

This chapter describes several different chemical and optical methods of determining the oxygen saturation of the blood which are more deterministic than the ones above. The chapter examines the development of oximetry from a historical perspective. The final section of the chapter gives an overview of the design of a pulse oximeter.

Some of the methods described in this chapter find the partial pressure of oxygen (PO_2) and some find the oxygen saturation (SO_2). Chapter 1 describes the relationship between these two. It is interesting to note from a historical perspective that SO_2 was not always an accepted means of reporting blood oxygenation. Gradwohl (1948) stated, 'Hemoglobin estimations are reported in terms of percentage, but this incorrect. They should always be reported in terms of grams per 100 mL.'

3.1 CHEMICAL METHODS

The oxygen content of blood can be determined from a sample by using chemical reactions to remove the oxygen from the blood. These measurements can be done with varying degrees of success. The chemical reactions can be slow also. The Van Slyke method can take up to 20 min.

22 *Design of pulse oximeters**3.1.1 Van Slyke method*

The Van Slyke apparatus (figure 3.1) is used in a method of measuring the oxygen content of a blood sample. A sample of blood is introduced to the apparatus anaerobically with a sample of potassium ferricyanide. Potassium ferricyanide is a releasing agent that releases the oxygen, carbon dioxide, and other gases from the blood sample. After removing the carbon dioxide from the mixture, the remaining gases are compressed into a fixed volume and the resulting pressure (P_1) is measured from the manometer. The oxygen is then absorbed with a reagent such as sodium hydrosulfite. The remaining gases are then recompressed into the same fixed volume and the final pressure (P_2) is measured (Hill 1966).

The difference of the two pressure measurements is a partial pressure due to the oxygen that was contained in the blood sample. The oxygen content of the blood sample is calculated by

$$\text{mL O}_2/100 \text{ mL blood} = K(P_1 - P_2) \quad (3.1)$$

where K is a constant relating to the reagents, apparatus, and the volume of the blood sample (Adams and Hahn 1982). Alternatively, the oxygen can be extracted from the blood with the Van Slyke apparatus and analyzed with a gas chromatograph (Hill 1966).

The technique is not simple to perform. Technical expertise and experience with chemical reactions are required to obtain accurate, reproducible results. However, the Van Slyke apparatus can provide measurements accurate to $\pm 0.03\%$ (Adams and Hahn 1982). The Van Slyke technique has been in the past a standard by which blood oxygen measurements were made (Miller 1966, Dennis and Valeri 1980).

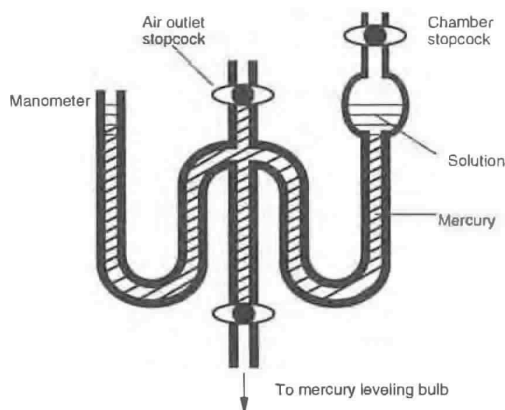


Figure 3.1 The Van Slyke apparatus (adapted from Adams and Hahn 1982).

3.1.2 Mixing syringe method

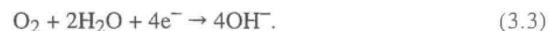
The mixing syringe method also measures the amount of oxygen released from a blood sample by a chemical reagent. The apparatus consists of two Luer-lock syringes joined to a manometer tap. One of the syringes is a precision automatic syringe which is able to accept and deliver a fixed volume of reagent. The automatic syringe is filled with the oxygen releasing agent and then emptied. This coats the inside of the syringe with the reagent and keeps the blood from any contact with the air. The oxygen releasing agent has a known oxygen partial pressure (P_r). The automatic syringe then draws a volume of blood (V_b) from the mixing syringe. The volume of blood and a known volume of the reagent (V_r) are mixed back and forth between the syringes. The partial pressure of oxygen of the blood-reagent solution (P_s) is then measured by a blood-gas analyzer. The oxygen content is calculated from the equation

$$\text{mL O}_2 / 100 \text{ mL blood} = \alpha \frac{V_r + V_b}{V_b} \left[P_s - \left(\frac{V_r}{V_r + V_b} P_r \right) \right] \quad (3.2)$$

where α is the solubility coefficient of oxygen in the blood-reagent solution at the temperature at which the measurement was made. Its value is obtained from either a separate experiment or from reference tables (Adams and Hahn 1982).

3.1.3 The Clark electrode

The Clark electrode uses the basic chemistry principles of oxidation and reduction to measure the PO_2 (partial pressure of oxygen) in a solution. When oxygen is dissolved in an aqueous solution and exposed to a 0.7 V polarizing voltage, the following reaction occurs



A silver anode immersed in a potassium chloride electrolyte bath will attract anions (Cl^-) to form silver chloride. This oxidation reaction produces a constant flow of electrons. A nearby platinum electrode undergoes a reduction reaction turning oxygen to hydroxyl ions (OH^-) as in equation (3.3). Figure 3.2 shows that the number of electrons used in the platinum cathode reaction is directly proportional to the PO_2 present in the bath. Therefore, by measuring the current between the two electrodes, the PO_2 in the solution is determined.

The entire Clark electrode system (figure 3.3) has a polypropylene sheath which slows the diffusion of oxygen from the blood to the electrode. This prevents the electrode from depleting the PO_2 in a particular place and eliminates the need to stir the blood *in vitro*.

The Clark electrode is the common sensing device used by blood gas analyzers to determine the PO_2 of the blood (Shapiro *et al* 1989). Using a variety of different electrodes, blood gas analyzers also determine the pH and PCO_2 of blood samples as small as 65 μL . The blood gas analyzers are very useful for *in vitro* measurements because they self-calibrate and self-diagnose malfunctions. Thus, interfacing blood gas analyzers with computers allows for automated measurements, patient data storage, and billing.

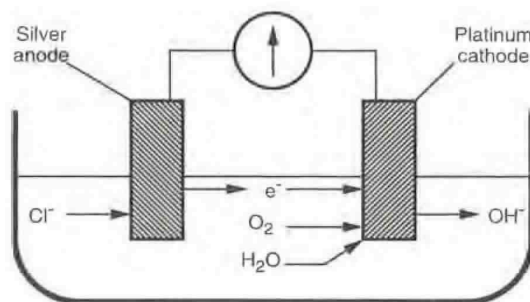
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Figure 3.2 Since an aqueous solution has plenty of H_2O and the silver anode is able to supply an abundance of electrons, equation (3.3) is limited by the amount of oxygen present. Thus, the amount of current between the anode and the cathode is determined by the PO_2 present. This reaction shows the chemical reaction that occurs in a Clark electrode.

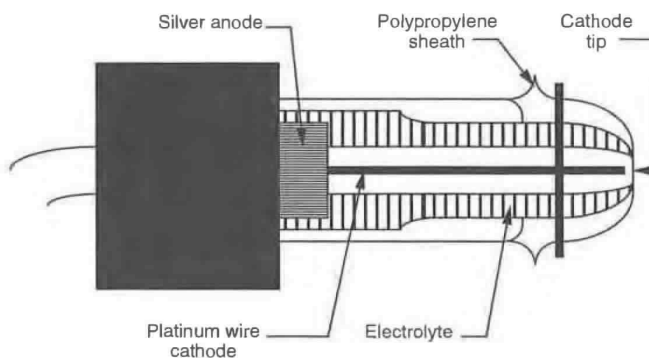


Figure 3.3 A Clark electrode (adapted from Shapiro *et al* 1989).

The Clark electrode can also be used to make *in vivo* measurements when designed to be used as catheter electrodes (Adams and Hahn 1982). Many catheter electrodes are designed specifically to be used with infants and are very small in diameter. Several different versions exist. Some versions have both the anode and cathode within the single electrode, as pictured in figure 3.3. But others have an external anode reference electrode on the skin.

One of the downfalls of the Clark electrode catheter system is calibration. Calibration takes place by drawing a blood sample near the end of the catheter and analyzing the sample with an *in vitro* blood gas analyzer. Another potential problem with the Clark electrode is keeping the tip clean. Though the polypropylene sheath helps to some extent, failure to keep the catheter in the flow of blood can cause errors as blood coagulates on the surface of the electrode.

3.1.4 The galvanic electrode

The galvanic electrode is similar in operation to the Clark electrode. As oxygen passes across the electrode, a chemical reaction occurs that produces a small electric current. But in this case the cathode is made of gold, the anode of lead, and the electrolyte solution is potassium hydroxide. In the Clark electrode, the silver anode and the platinum cathode participated in the chemical reaction. This made sure that the electrolyte solution was always replenished. But, the galvanic electrode has no means to replenish the electrolyte solution in the electrode and so it has a limited lifetime which depends on the PO_2 and exposure (Shapiro et al 1982).

3.2 TRANSCUTANEOUS PO_2 SENSOR

The Clark electrode can be used noninvasively to determine PO_2 of the blood. Under normal conditions, the PO_2 of the blood near the skin's surface ($P_{tc}O_2$, for the transcutaneous partial pressure of oxygen) is atmospheric. But, hyperemia of the skin can cause the $P_{tc}O_2$ to approach P_aO_2 , the arterial partial pressure. Hyperemia of the skin can be induced by drugs, creams, abrasions, or heating the skin. In other words, by placing a Clark electrode on the skin with a heating element, the skin begins to diffuse oxygen so that the $P_{tc}O_2$ is nearly equal to the P_aO_2 . The measurements given by the transcutaneous PO_2 electrode are stable with little drift and are widely accepted (Gothgen and Jacobsen 1987).

Heating is the easiest method of inducing hyperemia to control. With a heating element and a thermistor, the skin is heated to between 43 °C and 44 °C. This is the optimal temperature range for the $P_{tc}O_2$ to approach the P_aO_2 with minimal skin damage. The heat causes increased blood flow to the skin at the heating element site. This increased perfusion causes more O_2 to be delivered to this area and the excess O_2 diffuses through the skin more easily (Peura 1998). Figure 3.4 shows a cross sectional view of a transcutaneous PO_2 electrode, showing the heater and the thermistor.

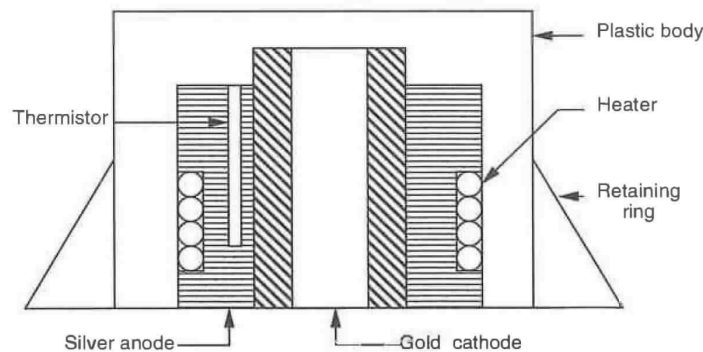


Figure 3.4 A cross section of a transcutaneous PO_2 electrode. The electrolyte below the anode and cathode is held in place by a polypropylene membrane.

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One advantage of the transcutaneous PO_2 electrode is that it measures the *real* $P_{tc}O_2$ and is not an empirical calculation as with the pulse oximeter (Gothgen and Jacobsen 1987). $P_{tc}O_2$ can be thought of as a new PO_2 variable and not an estimation of P_aO_2 . This contrasts with the pulse oximeter, which is an estimate of S_aO_2 , and whose accuracy is dependent on its ability to predict S_aO_2 (Barker and Tremper 1984). But again, one of the disadvantages of the transcutaneous PO_2 sensor is the calibration. Like the Clark electrodes used with catheters and blood gas analyzers, the transcutaneous PO_2 measurement is based on an electrochemical reaction that needs to be calibrated frequently with some gas mixtures.

The transcutaneous PO_2 electrode has other disadvantages. There is a warm up time of 10 min for the heating element to induce enough blood flow to the measurement site. And even with the thermistor regulating the heating element, there is a risk of burns, especially in infants. It is recommended that the electrode be moved every 4 hours (Burtis and Ashwood 1994).

The $P_{tc}O_2$ does not vary more than 5% from the P_aO_2 in infants but is more dependent on blood flow in adults. The heating is not as effective in adults and so the $P_{tc}O_2$ is usually lower than the P_aO_2 (Barker and Tremper 1984). Also, transcutaneous PO_2 electrodes are unreliable when the blood pressure falls below 100 mmHg or when some anesthetics such as nitrous oxide are administered (Burtis and Ashwood 1994). Even with these problems, the transcutaneous PO_2 electrode has been found useful in clinical situations in the operating room, intensive care units, and emergency rooms (Waxman *et al* 1983).

3.3 *IN VITRO* OXIMETERS3.3.1 *Spectrophotometers*

Spectrophotometry is the basis for all oximetry. The atoms of all molecules vibrate in specific patterns for each unique substance. As light passes through a substance, the frequencies of light similar to the vibrational frequencies of the substance are absorbed. A spectrophotometer measures the intensity of light transmitted through a particular substance at particular wavelengths. The fraction of light absorbed at a specific wavelength is determined by the absorptivity, or extinction coefficient, of the substance. The extinction coefficient of a substance can be graphed at various wavelengths as a spectrum. This spectrum is unique for every substance.

A photodetector is a device that converts light intensity into an electric current. A given intensity of light transmitted through a substance produces an electric current proportional to the intensity. By measuring the intensity of incident light on a substance (I_0) and measuring the intensity of light transmitted through the substance (I), the transmittance (T) of the substance can be calculated:

$$T = \frac{I}{I_0}. \quad (3.4)$$

Because each molecule absorbs an equal portion of light, the absorbance of light through a substance is linearly related to the concentration of substance

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present. From the measured transmittance (T), the absorbance (A) can be calculated from

$$A = 2 - \log (\%T). \quad (3.5)$$

Beer's law can now be used to find the amount of substance in a solution. Beer's law can be stated as

$$A = \varepsilon(\lambda) c d \quad (3.6)$$

where $\varepsilon(\lambda)$ is the extinction coefficient of the substance at a given wavelength λ of light, d is the length of the light path, and c is the concentration of the substance. For all substances, the linear relationship between absorbance and concentration only holds up to a certain concentration. Below this limit we can determine a calibration constant. The calibration constant can then be used as a standard to determine the unknown concentration of a substance with the same extinction coefficient as the standard.

For a solution with two unknown compounds, the absorbances at two wavelengths can be used to calculate the concentrations of both compounds. At the isosbestic point where the two extinction coefficients are equal, Beer's Law for the two samples can be written as

$$d = \frac{A_{ec}}{[c_1 + c_2] \varepsilon(\lambda_{ec})} \quad (3.7)$$

where A_{ec} is the absorbance at the isosbestic point and $\varepsilon(\lambda_{ec})$ is the extinction coefficient of the two substances at the isosbestic point. At the second wavelength Beer's Law gives

$$A_0 = d[c_1 \varepsilon_1(\lambda_0) + c_2 \varepsilon_2(\lambda_0)] \quad (3.8)$$

where A_0 is the absorbance and $\varepsilon_1(\lambda_0)$ and $\varepsilon_2(\lambda_0)$ are the extinction coefficients for the two compounds at the second wavelength. Because the sum of the concentrations of the two compounds is 1, we can solve equations (3.7) and (3.8) for the two concentrations.

If the solution contains more than just the two compounds as is the case with oximetry, solving equations (3.7) and (3.8) will give the relative concentration of c_1 to c_2 if the assumption can be made that none of the other compounds will absorb light at the two wavelengths used for the measurement. This assumption is sufficient for oximetry where the relative concentrations of Hb and HbO₂ are used to estimate S_aO₂.

Note that measuring the absorbance at the isosbestic point is not necessary to solve for c_1 and c_2 . The absorbance at any two wavelengths can be used to solve for the concentrations with equally good results. The motives for the choice of the isosbestic point as one of the wavelengths used in the earliest oximeters are not clear. But the simplified mathematics may have been a reason (Nilsson 1960).

With the concentrations of Hb and HbO₂, an estimation of S_aO₂ is made from

$$S_pO_2 = \frac{HbO_2}{HbO_2 + Hb} \times 100\% \quad (3.9)$$

This assumes that any other substance present in the solution being measured has no effect on the absorbance of light at the chosen wavelengths. For example, it does not take into account the effect of the other types of hemoglobin present in the blood. These hemoglobin species do absorb light at certain wavelengths, but their relative concentration with respect to Hb and HbO₂ is small enough that for many applications equation (3.9) is an accurate estimate.

3.3.2 The CO-oximeter

CO-oximeters are spectrophotometers specifically designed to analyze the concentrations of several different types of hemoglobin including reduced hemoglobin (Hb), oxyhemoglobin (HbO₂), carboxyhemoglobin (COHb), and methemoglobin (MetHb). Each of these various forms of hemoglobin has its own extinction coefficient curve (figure 4.2). By using as few as four wavelengths of light, the amount of each of these forms of hemoglobin can be determined from a sample.

Instrumentation Laboratories Inc. coined, but did not copyright, the term CO-oximeter and released the first commercial CO-oximeter in 1966 (Moyle 1994). The CO-oximeter was originally introduced to measure COHb using three different wavelengths, 548 nm, 568 nm and 578 nm (Adams and Hahn 1982). The IL-282 CO-oximeter pictured in figure 3.5 uses four wavelengths of light, 535.0 nm, 585.2 nm, 594.5 nm, and 626.6 nm, to measure all four of the relevant forms of hemoglobin. These wavelengths are obtained by four interference filters mounted on a rotating wheel each selecting wavelengths of light from a Ti-Ne hollow cathode lamp (Zwart *et al* 1981). The CO-oximeter is able to operate in this narrow range of light because it only works with diluted plasma samples and like pulse oximeters does not have to deal with skin, muscle, or other tissue (Moyle 1994).

A four wavelength CO-oximeter would obtain absorbance readings on a blank solution at all four different wavelengths (λ_{1-4}). Then a reading is obtained at each wavelength for a diluted, hemolyzed sample. CO-oximeters use hemolyzed samples, blood samples with the red blood cell membranes removed, to reduce the amount of light scattering, which reduces the accuracy of the measurement.

The absorbance readings of the blank solution are subtracted from the readings from the samples at each wavelength to give the absorbance of the blood at each wavelength. From these absorbances of the blood, the concentration of each type of hemoglobin can be calculated from the equations

$$C_{Hb} = K[\epsilon_{Hb}(\lambda_1)A_1 + \epsilon_{Hb}(\lambda_2)A_2 + \epsilon_{Hb}(\lambda_3)A_3 + \epsilon_{Hb}(\lambda_4)A_4] \quad (3.10)$$

$$C_{HbO_2} = K[\epsilon_{HbO_2}(\lambda_1)A_1 + \epsilon_{HbO_2}(\lambda_2)A_2 + \epsilon_{HbO_2}(\lambda_3)A_3 + \epsilon_{HbO_2}(\lambda_4)A_4] \quad (3.11)$$

$$C_{MetHb} = K[\epsilon_{MetHb}(\lambda_1)A_1 + \epsilon_{MetHb}(\lambda_2)A_2 + \epsilon_{MetHb}(\lambda_3)A_3 + \epsilon_{MetHb}(\lambda_4)A_4] \quad (3.12)$$

$$C_{COHb} = K[\epsilon_{COHb}(\lambda_1)A_1 + \epsilon_{COHb}(\lambda_2)A_2 + \epsilon_{COHb}(\lambda_3)A_3 + \epsilon_{COHb}(\lambda_4)A_4] \quad (3.13)$$

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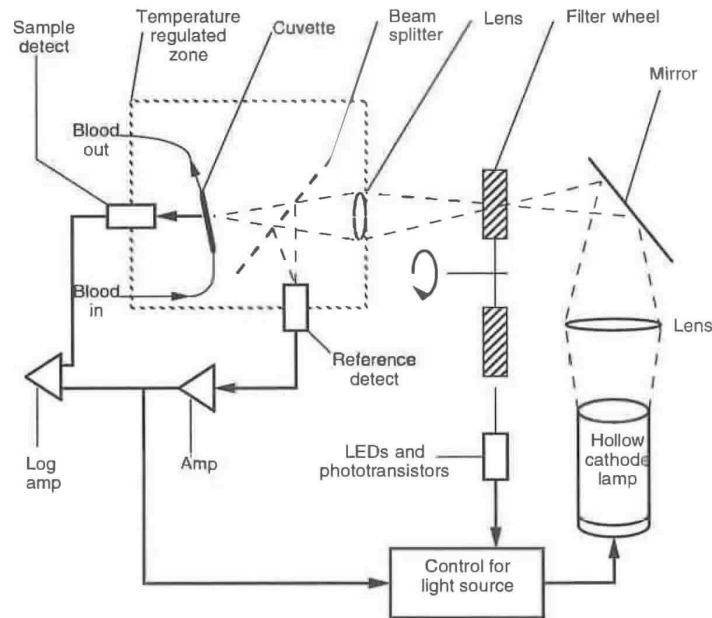


Figure 3.5 A schematic diagram of the IL-282 CO-oximeter (adapted from Zwart *et al* 1981).

where C_x is the concentration of hemoglobin type x , $\epsilon_x(\lambda_1)$ is the extinction coefficient of hemoglobin type x at the first wavelength, A_1 is the difference between the absorbance value of the blood and the blank solution at the first wavelength, and K is a constant set by the calibration procedure (Shapiro *et al* 1989).

CO-oximeters are subject to many sources of error. Any substances in the sample that scatter light affect the measurements because the amount of light transmitted is no longer solely a function of the light absorbed by hemoglobin species. Samples infected with small portions of lipids or cell fragments are common causes of light scattering. There are also errors associated with fetal hemoglobin samples. Results from CO-oximeters have been known to give falsely high COHb readings in fetal hemoglobin (Zwart *et al* 1981). Some CO-oximeters try to compensate for these errors by using more wavelengths of light. For example the AVL 912 uses 17 wavelengths to try to compensate for other light absorbing fragments that might be present in the solution (Moyle 1994).

Because CO-oximeters make measurements *in vitro* with discrete samples, they provide accurate oxygen saturation readings for only the times at which the samples are drawn. They do have their uses, notably as a standard for calibration of *in vivo* oximeters (Moyle 1994). The CO-oximeter is one of the most accurate methods available for measuring the four clinically relevant hemoglobin species. It is a standard against which other methods of measurement are compared (Shapiro *et al* 1989).

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3.4 *IN VIVO* TWO-WAVELENGTH OXIMETERS

3.4.1 *The first in vivo oximeters*

In vivo oximetry originated in Germany in the 1930s when the use of the selenium photovoltaic cell became accepted (Peterson 1986). In 1934, Kramer showed that the absorbance of red light depended on oxygen saturation, but his implementation only used one wavelength of light (Payne and Severinghaus 1986). At about the same time, Matthes designed an oximeter which measured the transmission of light through the ear by a lamp with a photocell attached to the earlobe. At the time, regions of optical spectra were broadly defined and depended greatly on the lamp, photocell, and filters used. Matthes used wavelengths of red light, which varied the transmission measurements as the oxygen saturation varied, and compared them to measurements using green light, which did not vary with saturation. He later discovered that infrared light was a better choice than green (Nilsson 1960).

Glen Millikan is credited with coining the term oximeter while, during World War II, attempting to design a hemoglobin saturation meter for the ears of pilots to control the amount of oxygen they received (Severinghaus 1987). Millikan's ear piece was improved by Wood and Geraci in 1949. The biggest improvement was in the infrared filter. They also had the idea of using an inflatable balloon to cut off the circulation to the ear and make it bloodless. This made for a zero setting which tried to account for the other tissue present in the ear. Wood thought he had succeeded in the first absolute reading oximeter but he later showed that inconsistencies in the photocells used for light detection caused the device to be inaccurate (Payne and Severinghaus 1986).

3.4.2 *The Cyclops*

The Cyclops was a commercially available reflectance oximeter. It was named the Cyclops because of the large sensing device that was placed on the forehead of the patient. It used red and green light to determine SO_2 . Limitations in the technology of photocells limited the Cyclops from using infrared light. The theory of the device was based on the fact that any reflection of the green light was due to nonblood reflection. The reflection of the red light was due to both the blood and noncomponents. So, by subtracting the green light reflection from the red light reflection, the reflection due to the blood was found.

The Cyclops was successful in producing trending information about SO_2 . And if it was calibrated against two or more arterial blood samples, the Cyclops could produce accurate SO_2 values (Zijlstra 1958).

3.5 FIBER OPTIC OXIMETERS

3.5.1 *In vitro reflectance oximeter*

Polanyi and Hehir (1962) first described the design of a fiber optic oximeter to use as a catheter measurement device. They also used two wavelengths of light to measure the concentrations of Hb and HbO_2 . They chose the specific values for

their wavelengths of light to be 660 nm and 805 nm; 805 nm is the isosbestic point of HbO₂ and Hb. They used a filter wheel, similar to the one used in the CO-oximeter in figure 3.5, to obtain their wavelengths.

The concentrations of Hb and HbO₂ can be calculated in the same manner as in section 3.3.1. The only difference with this device is that this fiber optic oximeter was a reflectance device and measured an absorbance directly from the backscattered light in the blood. In Section 3.3.1, the measurement was a transmittance of light which was converted to an absorbance.

Polanyi and Hehir presented successful results with their fiber optic oximeter with *in vitro* experiments. But although they intended their device to be used *in vivo*, it did not come to be (Barker 1991).

3.5.2 *In vivo* reflectance catheter oximeter

In vivo catheter oximeters were not in widespread use until about 1980. These *in vivo* fiber optic catheter oximeters use much the same technology as the pulse oximeter. Many catheter oximeters are two-wavelength devices like the pulse oximeter. Some of them use three wavelengths to try to compensate for changes in pH or other variables. Figure 3.6 shows the basic configuration of a fiber optic reflectance oximeter.

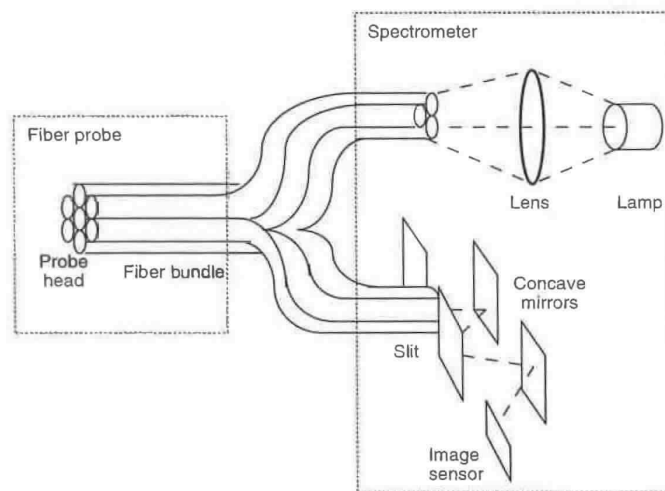


Figure 3.6 A fiber optic reflectance catheter oximeter (adapted from Ono *et al* 1991).

These devices do require user calibration though. The calibration can be done with a CO-oximeter or by the preferred method of *in vivo* calibration. Drift can occur after several hours and the catheter may need to be recalibrated.

Some of the early fiber optic catheters had the problem of wall artifacts, where reflections of light from a vessel wall would cause erroneous values of S_vO₂. New digital filtering techniques have helped to reduce that problem. Early

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catheters had a reputation for being stiff and hard to insert, but the use of plastic fiber optics has helped this issue (Barker 1991).

The early fiber optic oximeters were designed for cardiac catheterization to measure S_vO_2 . Features have been added to some fiber optic probes for other uses. For example, some probes have a contact sensor or a pressure sensor to sense contact with tissue. This allows more stable data from *in vivo* tissue because the probe head can avoid excessive pressure which would affect microcirculation. Another application for the fiber optic oximeter is as a dental tool to diagnose SO_2 of gingiva (Ono *et al* 1991).

3.5.3 *In vivo chemical oximeter*

Peterson and Fitzgerald (1984) describe a chemical fiber optic oximeter suitable for measuring P_aO_2 . A fluorescent dye in the tip of the probe reflects light sent by the oximeter back to a sensor. The dye has a unique property that it loses its luminescence in the presence of oxygen. Figure 3.7 shows the chemical fiber optic probe. The difference between this probe and the reflectance fiber optic probe is a small one. The reflectance fiber optic probe measures the change in color of the blood by reflecting light from it. This change in color indicates the degree of saturation. This device measures the change in color of a substance that changes color in the presence of oxygen.

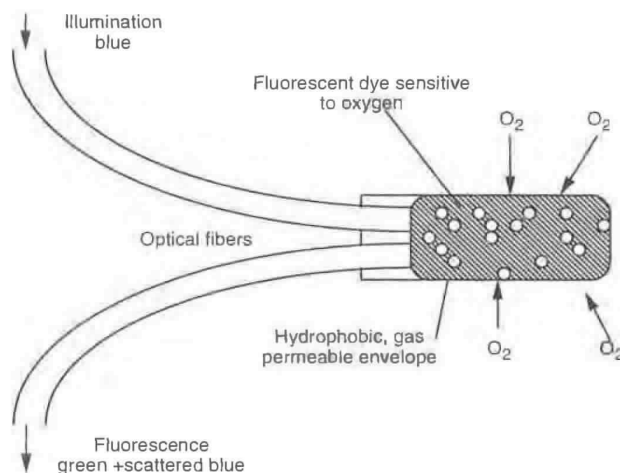


Figure 3.7 This figure shows the probe end of a chemical fiber optic oximeter. The coloration of the probe end changes in response to the amount of oxygen present.

3.6 *IN VIVO* EIGHT-WAVELENGTH OXIMETER

In 1970, Hewlett-Packard marketed an eight-wavelength oximeter, model 47201A. The device was designed to overcome some of the problems of the two-wavelength oximeter. It was designed to be self calibrating, accounted for factors

like skin pigmentation, and claimed to be unaffected by motion (Merrick and Hayes 1976). The device also claimed to be precalibrated requiring no test samples. The only calibration necessary was an infrequent procedure that gave reference values of light intensity to the device, and did not involve the patient.

Figure 3.8 shows a block diagram of the 47201A. The lamp is a tungsten-iodine lamp which has a high output of light in the wavelengths of interest (650 nm to 1050 nm). The desired wavelengths are obtained with light filters. The filters are mounted on a rotating wheel so they cut the light beam sequentially. The wheel spins at 1300 rpm so about 20 samples at each wavelength are obtained every second.

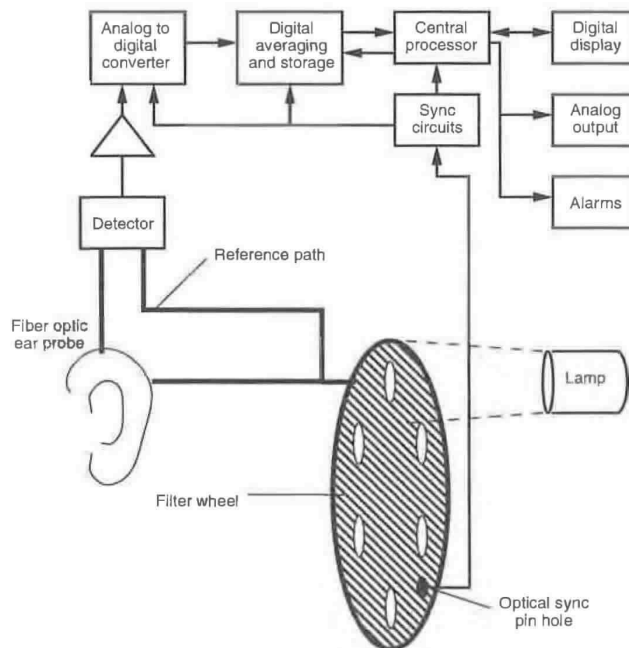


Figure 3.8 Block diagram of the Hewlett-Packard Model 47201A eight-wavelength ear oximeter.

The filtered light travels down two fiber optic paths. The first path leads directly to the photodetector and acts as a reference. This prevents any variations in the measurements due to changes in the light source or slight variations in the filters. The second fiber optic path goes to the ear probe. The filtered light is transmitted through the ear to a fiber optic cable which carries it to the photodetector. The current produced by the photodetector may be on the order of 0.5 nA so the output of the photodetector is amplified by a factor of 10^8 . The absorbance is derived from the difference between the reference intensity and the intensity of the light transmitted through the ear.

For a time, the Hewlett-Packard device was the gold standard for oximeters. It worked fairly well and was the first introduction of noninvasive oximetry into

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a clinical environment. But it was found to be inaccurate for saturations less than 70%. And though it was a large improvement over previous devices, the Hewlett-Packard device was not totally immune to motion artifacts or skin pigmentation as it claimed. Also, it still required that the probe heat the skin. Devices that heat the skin put the patient at risk of burns, especially infants who have sensitive skin.

Although giving an improvement in performance, the device was huge, weighing almost 17 kg. The ear probe was also quite large and the fiber optics were fragile. Though it was the *gold standard* of oximeters in its time (Moyle 1994) it was used clinically only in sleep studies, pulmonary medicine, and physiology. The HP eight-wavelength oximeter was never used in anesthesiology or critical care as the pulse oximeter is today. Its use declined even more with improvements in the Clark transcutaneous PO_2 electrode (Severinghaus 1987).

3.7 PULSE OXIMETERS

The idea of exploiting the pulsatile nature of arterial blood in oximetry first belonged to Takuo Aoyagi while working in Japan for Nihon Kohden Corporation (Severinghaus 1987). Nihon Kohden's device used analog circuitry, had bulky fiber optic cables, and still had some of the instability problems of the Hewlett-Packard device. Other companies such as Minolta came up with similar products with similar problems (Santamaria and Williams 1994).

An anesthesiologist named William New saw the pulse oximeter marketed by Minolta and saw how to improve it. New, also an electrical engineer, teamed with Jack Lloyd to found Nellcor, Inc. Nellcor produced a microprocessor-based pulse oximeter, the N100, which was smaller, less expensive, needed no user calibration, and was accurate enough for clinical use. Nellcor is still the market leader in pulse oximetry (Santamaria and Williams, 1994). About the same time, Ohmeda came up with a similar device, the Biox II, which had similar success (Wukitsch *et al* 1988). Today, pulse oximeters exist in every intensive care unit, surgical suite, and in many emergency rooms in the United States (Santamaria and Williams 1994).

This section gives a brief description of the major parts of a pulse oximeter. Further detail of each of these parts can be found in later chapters.

3.7.1 Overview

By taking advantage of the pulsatile flow of blood, the pulse oximeter is able to overcome many of the problems of earlier technologies. The pulse oximeter tracks the change in light absorbance as the blood pulses. By tracking this peak-to-peak ac component, the absorbance due to venous blood or tissue does not have any effect on the measurement.

Light scattering is still a source of inaccuracy in pulse oximeters. Beer's law does not account for the scattering of light. So a direct calculation of S_aO_2 is not possible. The pulse oximeter measures absorbances at the two wavelengths and uses data from CO-oximeters to empirically look up a value for S_pO_2 , an estimation of S_aO_2 .

3.7.2 LEDs

One of the large improvements of the pulse oximeter over earlier oximeters is the use of LEDs as the light source. The LEDs can transmit large intensities of light proportional to the amount of drive current. The LED control block in figure 3.9 controls the amount of drive current and the timing of the LEDs. The timing of the pulsations is critical because the photodiode cannot distinguish between different wavelengths of light. The pulse oximeter relies on the microprocessor system to synchronize the pulsations of the LEDs with the samples taken by the ADC so that the absorbances detected by the photodiode can be attributed to the correct LED.

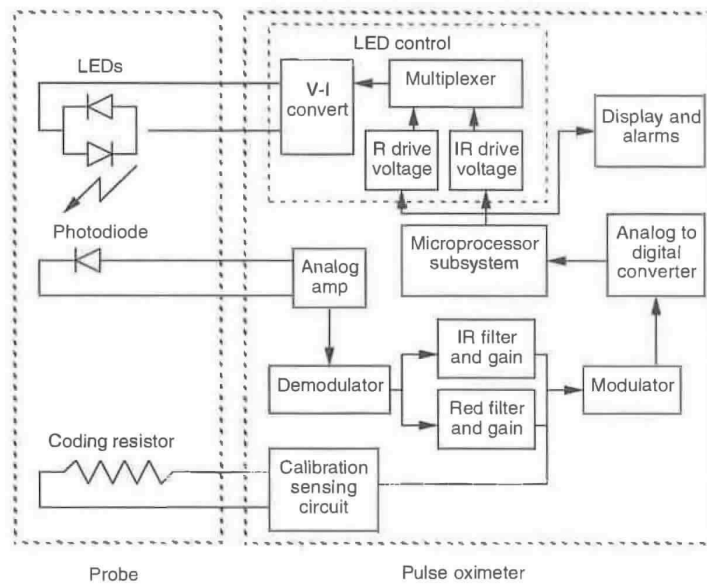


Figure 3.9 Block diagram of a pulse oximeter system. The arrows show the flow of data. The microprocessor also provides control and timing for the demodulator, modulator, and LED control circuits.

The two wavelengths chosen for pulse oximetry are 660 nm and 940 nm. These wavelengths were chosen based on the availability of LEDs at these wavelengths and because the extinction coefficients of Hb and HbO₂ vary as much as possible. HbO₂ has a higher extinction coefficient than Hb at 940 nm and a lower extinction coefficient at 660 nm. In other words, as S_aO₂ increases, the absorbance of light increases at 940 nm and decreases at 660 nm.

One disadvantage of using LEDs as a light source is that the exact wavelength of any single LED can vary by as much as ± 15 nm. This would cause significant errors if unaccounted for. To account for this, some manufacturers characterize each LED and code it with a resistor value. By driving the coding resistor (figure 3.9) with a constant current source, the pulse oximeter can

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measure the voltage and take the characterization of the LEDs into account when empirically calculating S_pO_2 (Pologe 1987).

3.7.3 *Photodiode*

The photodetector is a silicon photodiode that produces current linearly proportional to the intensity of light striking it. Advances in silicon technology allow the photodiode to be small enough to fit in small, finger tip probes. These advances have helped make the pulse oximeter much more accurate and convenient than earlier devices. Early oximeter devices needed frequent calibration because the photoelectric devices used as sensors were often inconsistent (Miller 1966).

A photodiode cannot distinguish between red and infrared light, but to accommodate this, the microprocessor system alternately turns each LED on and off. The pulse oximeter repeatedly samples the photodiode output while the red LED is on, while the infrared LED is on, and while both are off. By sampling with both LEDs off, the pulse oximeter is able to subtract any ambient light that may be present (Pologe 1987).

3.7.4 *Probes*

Improved technology in photodiodes and LEDs has another benefit. They allow the probe to be small and attach to the pulse oximeter with conventional wires. The Hewlett-Packard eight wavelength oximeter was considered an accurate device, but because bulky fiber optic cables were needed to carry the light source to the patient and the transmitted light back to a light sensor, it was impractical (Rebuck *et al* 1983). Probes for the pulse oximeter are not only smaller, but can be disposable.

Figure 3.10 shows a transmission pulse oximeter and a reflectance pulse oximeter. As the names indicate, a transmission pulse oximeter measures the amount of light that passes through the tissue as in a finger probe. A reflectance pulse oximeter measures the amount of light reflected back to the probe. Both types use the same technology differing only in positioning of the probes and calibration.

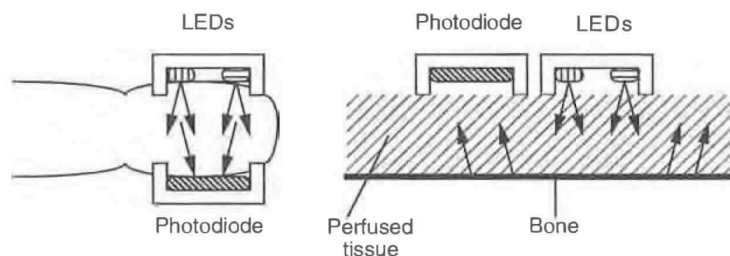


Figure 3.10 On the left is a transmission pulse oximeter measuring the transmission of light by two LEDs through the finger of a patient. On the right is a reflectance pulse oximeter measuring the amount of light reflected back to the probe.

3.7.5 Analog amplifier and signal processing

The photodiode generates a current proportional to the intensity of light. The analog amplifier converts this current to a voltage. Because the change in voltage due to the pulsations of the arteries is small in comparison to the dc portion of the signal, the dc component of the signal is subtracted from the rest of the signal by the demodulator. The demodulator also uses a sample-and-hold timing circuit to separate samples from the red LED from the samples of the infrared LED. The ac portions of these signals are low-pass filtered to remove electromagnetic interference. Then each signal goes through a programmable gain circuit after which a multiplexer with another sample-and-hold circuit modulates the red and infrared signals back into one to go through an analog-to-digital converter (ADC) for use by the microprocessor.

Using the data gathered from the ADC, the microprocessor calculates what is called a ratio of ratios. From this ratio of ratios and the value of the coding resistor, the microprocessor goes to an empirical look up table for its S_pO_2 value. The empirical look up table is generated by the manufacturer through laboratory tests done with a CO-oximeter. The signal processing algorithms also provide some noise reduction. Some pulse oximeters use an ECG in their signal processing algorithm to minimize errors due to motion artifacts.

3.7.6 A three-wavelength pulse oximeter for COHb determination

Current pulse oximeters estimate the arterial oxygen saturation of the blood by measuring absorbances at two wavelengths of light. Because of this, the pulse oximeter is only able to account for Hb and HbO₂. Increased levels of COHb, for example, will cause an overestimation in S_aO_2 because the pulse oximeter cannot distinguish between HbO₂ and COHb. In cases of carbon-monoxide poisoning, this could have terrible consequences if the clinician is unaware.

Table 3.1 A comparison of pulse oximetry and transcutaneous PO_2 electrodes from New (1985), Barker and Tremper (1984), and Severinghaus (1987).

Pulse oximeters	Transcutaneous $P_{tc}O_2$ electrodes
Require no heating	Have internal heaters which can cause burns and must be moved periodically to avoid skin damage, especially in infants
Have no delay	Require skin and electrode preparation and a warm up period of up to ten minutes
Never require user calibration	Require recalibration
Probes are clipped or taped on	Require operator skill to place monitor
Measure a pure respiratory variable (S_aO_2) and a pure circulatory variable (plethysmograph)	Are a sensitive, but not specific, monitor of blood oxygenation; a drop in $P_{tc}O_2$ may be caused by respiratory deficiency, circulatory deficiency, or both
Give an accurate reading or none at all	Report low PO_2 when electrode may not be placed well
Require pulsating arteries; fails during cardiac arrest, cardiopulmonary bypass, or distal placement to blood pressure cuff.	Detect low cardiac output
Require hemoglobin in the bloodstream and may fail with severe anemia or hemodilution	Are not dependent on hemoglobin
Can be in error with high levels of dyshemoglobin species present in the blood	
Display pulse rate	Do not display pulse rate

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Buinevicius (1987) designed a three wavelength pulse oximeter to solve this problem. An additional LED at 810 nm was used in an attempt to determine the amount of COHb in the blood. Buinevicius also presented a method to calibrate the pulse oximeter for three wavelengths using three-dimensional solutions to Beer's law.

3.7.7 *Comparison of pulse oximetry to transcutaneous PO₂ electrodes*

Pulse oximeters and transcutaneous PO₂ electrodes are the two main technologies used to provide continuous information about the supply of oxygen to the body. Table 3.1 provides a comparison between the two technologies.

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INSTRUCTIONAL OBJECTIVES

- 3.1 Explain why transcutaneous PO_2 electrodes require the skin to be heated.
- 3.2 Explain why a CO-oximeter uses hemolyzed blood samples to determine the hemoglobin components of the blood.
- 3.3 Explain the difference between absorptivity and absorbance.
- 3.4 Describe a noninvasive two-wavelength oximeter and its problems.
- 3.5 Describe a two-wavelength fiber optic oximeter.
- 3.6 Describe an eight-wavelength oximeter.
- 3.7 Describe how pulse oximeters overcome some of the problems of earlier oximeters.
- 3.8 Explain the need for a coding resistor in a pulse oximeter probe.
- 3.9 Explain why Beer's law cannot be used for direct computation of S_pO_2 and empirical lookup tables are used instead.
- 3.10 Given the concentrations of oxyhemoglobin and reduced hemoglobin for blood, calculate S_pO_2 .
- 3.11 Explain why a pulse oximeter might not be as accurate for a patient who is a smoker.
- 3.12 Describe a three-wavelength pulse oximeter to determine COHb concentration and explain it might be more accurate for a patient who is a smoker than a two-wavelength pulse oximeter.

CHAPTER 4

LIGHT ABSORBANCE IN PULSE OXIMETRY

Oliver Wieben

This chapter describes the theoretical background for the measurement of light absorbance in pulse oximetry as a basis for determining arterial oxygen saturation. Beer's law and the derivation of a theoretical calibration curve for measured light absorbances in pulse oximeters is explained, although this curve is not valid in practice due to the scattering of light. Beer's law is used accurately to determine the oxygen saturation of hemoglobin solutions but does not apply for whole blood because of the scattering effects. Nevertheless, this model helps to develop an understanding of the absorbance of light as it passes through living tissue and why and how pulse oximetry works. The normalization of the measured signals and the calibration curves used in pulse oximeters are explained after an introduction of the theoretical model. The final part of the chapter describes mathematical approaches to incorporate light scattering in the model and describe its effects qualitatively and quantitatively.

4.1 BEER'S LAW

Beer's law (also referred to as Beer–Lambert's or Bouguer's law) describes the attenuation of light traveling through a uniform medium containing an absorbing substance. If monochromatic incident light of an intensity I_0 enters the medium, a part of this light is transmitted through the medium while another part is absorbed. The intensity I of light traveling through the medium decreases exponentially with distance

$$I = I_0 e^{-\varepsilon(\lambda)cd} \quad (4.1)$$

where $\varepsilon(\lambda)$ is the *extinction coefficient* or absorptivity of the absorbing substance at a specific wavelength, c the concentration of the absorbing substance which is constant in the medium, and d the optical path length through the medium (see figure 4.1). The concentration c is measured in mmol L^{-1} and the extinction coefficient is expressed in $\text{L mmol}^{-1} \text{cm}^{-1}$.

Beer's law is based on the property that the sum of transmitted and absorbed light equals the incident light. It does not account for physical processes which include reflection of the light at the surface of the medium or scattering of light in the medium.

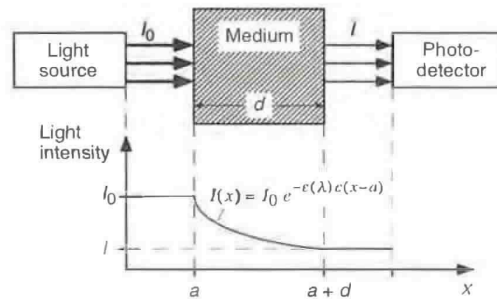


Figure 4.1 Beer's law: Incident light of intensity I_0 travels the distance a from a light source to the medium without being absorbed in the air. The light intensity decreases exponentially with distance in the absorbing medium. The intensity of the transmitted light I is determined by Beer's law. It stays constant after exiting the medium with optical path length d and can be measured by a photodetector.

4.1.1 Transmittance and absorbance of light

The *transmittance* (T) of light traveling through a medium with an absorbing substance is defined as the ratio of transmitted light I to the incident light I_0

$$T = \frac{I}{I_0} = e^{-\epsilon(\lambda)cd}. \quad (4.2)$$

The *unscattered absorbance* (A) of this process is defined as the negative natural logarithm of the transmittance of light

$$A = -\ln T = \epsilon(\lambda)cd. \quad (4.3)$$

The absorbance is sometimes referred to as the optical density of a medium.

4.1.2 Multiple absorbers

The properties of Beer's law are valid even if more than one substance absorbs light in the medium. Each absorber contributes its part to the total absorbance. The mathematical representation of this system of absorbers is a superposition of the individual absorbing processes. The resulting *total absorbance* A_t of light in a medium with n absorbing substances is the sum of their n independent absorbances

$$A_t = \epsilon_1(\lambda)c_1d_1 + \epsilon_2(\lambda)c_2d_2 + \dots + \epsilon_n(\lambda)c_nd_n = \sum_{i=1}^n \epsilon_i(\lambda)c_id_i \quad (4.4)$$

where $\epsilon_i(\lambda)$ and c_i represent the extinction coefficient and concentration of the substance i and d_i represents the optical path length through the absorbing substance, which may differ from substance to substance in the medium.

Therefore, Beer's law allows us to determine the unknown concentrations of n different absorbing substances in a homogeneous medium if the absorbance of light is measured at n different wavelengths and the extinction coefficients of the substances are known.

4.2 HEMOGLOBIN EXTINCTION COEFFICIENTS

Hemoglobin is the main light absorber in human blood at wavelengths used in pulse oximetry. The absorbing characteristics of hemoglobin change with its chemical binding and the wavelength of the incident light. Although oxygenated and reduced hemoglobin absorb most of the light passing through blood, they do not represent the only two hemoglobin species present in human blood. Hemoglobin may combine with other substances such as carbon monoxide or hydrogen sulfide as well, which changes its color.

4.2.1 Functional hemoglobins

Binding oxygen in the pulmonary capillaries and releasing it in the systemic capillaries is the main purpose of hemoglobin. Hemoglobins that are able to bind reversibly with molecular oxygen are called *functional hemoglobins*.

When hemoglobin is fully saturated with oxygen (carrying four oxygen molecules), it is called *oxyhemoglobin* (HbO_2). If it is not fully saturated with oxygen it is called *reduced hemoglobin* (Hb). Therefore oxyhemoglobin and reduced hemoglobin are functional hemoglobins.

Most of the hemoglobins in a healthy individual are functional hemoglobins. The *functional oxygen saturation* (functional SO_2) is measured in percentage and determined by the amount of oxygenated hemoglobin (HbO_2) as compared to the sum of oxygenated and reduced hemoglobin (Hb). Another way to define this ratio is to use the concentrations of oxygenated hemoglobin (c_{HbO_2}) and reduced hemoglobin (c_{Hb})

$$\text{Functional } \text{SO}_2 = \frac{\text{HbO}_2}{\text{Hb} + \text{HbO}_2} \times 100\% = \frac{c_{\text{HbO}_2}}{c_{\text{HbO}_2} + c_{\text{Hb}}} \times 100\%. \quad (4.5)$$

The functional oxygen saturation of explicitly arterial blood is called functional arterial oxygen saturation (functional S_aO_2) and is referred to as functional hemoglobin saturation as well.

4.2.2 Dysfunctional hemoglobins

Dysfunctional hemoglobins (or dyshemoglobins) do not support the transport of oxygen to the tissues. They are either unable to bind reversibly to oxygen or interfere with the ability of oxyhemoglobin to release its oxygen to the tissue.

The four most common dyshemoglobins are methemoglobin (MetHb), carboxyhemoglobin (COHb), sulfhemoglobin, and carboxysulfhemoglobin.

4.2.2.1 Methemoglobin. Methemoglobin is oxidized hemoglobin. It is a result of oxidation of a free heme iron (Fe^{2+}) instead of the reversible binding of oxygen to heme inserted into globin subunits.



An enzyme system (including cytochrome b₅) is responsible for reducing the methemoglobin in the red cells by maintaining hemoglobin in the reduced state (Fe²⁺).

Oxidized hemoglobin subunits are not capable of binding oxygen and altering the oxygen binding of the remaining ferrous hemes. Therefore, methemoglobin has a great influence on the functionality of hemoglobin. Under physiological circumstances the amount of methemoglobin remains below 0.6% of the total hemoglobin and this amount varies at a rate of 2 to 3% during the day. The absorbance spectrum of methemoglobin is strongly pH-dependent (Bunn 1986).

4.2.2.2 Carboxyhemoglobin. Carboxyhemoglobin is formed when hemoglobin combines with carbon monoxide (CO). The carbon atom of carbon monoxide is bonded to the iron atom of heme.

The affinity of hemoglobin binding with carbon monoxide is approximately 210 times larger than that of oxygen. Therefore, the presence of a high level of carbon monoxide will reduce the amount of oxygenated hemoglobin significantly. The level of carboxyhemoglobin in the blood varies with the habits and surroundings of the individual. Smoking, working in underground garages, traffic tunnels, mines, etc. increases the amount of CO in the blood. In nonsmokers the level of COHb is usually below 2% but this value varies with the local environment (Wukitsch *et al* 1988).

4.2.2.3 Sulfhemoglobin and carboxysulfhemoglobin. The reaction of oxyhemoglobin and hydrogen sulfide produces sulfhemoglobin. The relevant chemical reactions are complex and not thoroughly understood, although the absorbance spectrum of sulfhemoglobin is known.

The oxygen affinity of the heme iron in sulfhemoglobin is 100-fold lower than the oxygen affinity of unmodified hemoglobin (Bunn 1986). This chemical reaction is irreversible (Nellcor 1993). Carboxysulfhemoglobin results from a reaction of sulfhemoglobin with carbon monoxide. The concentrations of sulfhemoglobin and carboxysulfhemoglobin in human blood are usually not significant.

4.2.2.4 Fractional hemoglobin saturation. The fractional oxygen saturation is the fraction of oxygenated hemoglobin to the total hemoglobin. It is usually measured in percentage as well and is determined by the ratio of the concentrations of oxygenated hemoglobin to total hemoglobin

$$\text{Fractional } \text{SO}_2 = \frac{c_{\text{HbO}_2}}{c_{\text{total hemoglobin}}} \times 100\% \quad (4.7)$$

where total hemoglobin represents all different species of hemoglobin present in the blood.

4.2.3 Hemoglobin absorbance spectra

The chemical binding of the different hemoglobin species changes the physical properties of the hemoglobin as well. Figure 4.2 shows the extinction coefficients of oxyhemoglobin, reduced hemoglobin, methemoglobin and carboxyhemoglobin at wavelengths in the range of interest in pulse oximetry.

The absorbance of light in the red region of the spectrum is much higher for reduced hemoglobin than for oxyhemoglobin. The extinction coefficients of both hemoglobin species are equal at the point isosbestic point (805 nm). The reduced hemoglobin is more transparent to light from the infrared region than oxyhemoglobin.

The extinction coefficient of carboxyhemoglobin is about the same as that of oxyhemoglobin at the wavelength of 660 nm while it is almost transparent in the infrared region. Methemoglobin absorbs much light in the red region of the spectrum and its extinction coefficient remains higher than that of oxyhemoglobin in the infrared region.

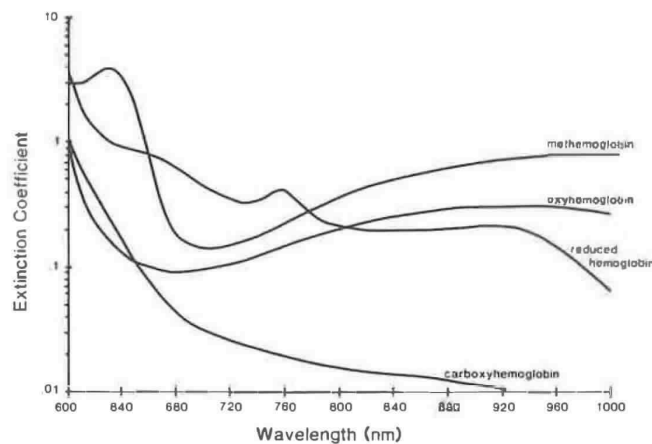


Figure 4.2 Extinction coefficients of the four most common hemoglobin species oxyhemoglobin, reduced hemoglobin, carboxyhemoglobin, and methemoglobin at the wavelengths of interest in pulse oximetry (courtesy of Susan Manson, Biox/Ohmeda, Boulder, CO).

4.3 BEER'S LAW IN PULSE OXIMETRY

Pulse oximeters determine the oxygen saturation of arterial blood by measuring the light absorbance of living tissue at two different wavelengths and using the arterial pulsation to differentiate between absorbance of arterial blood and other absorbers.

4.3.1 Criteria for the choice of wavelengths

Different reasons lead to the most common choice for wavelengths used in pulse oximetry. The red skin pigmentation absorbs a great amount of light at wavelengths shorter than 600 nm and therefore it is not desirable to measure light absorbance in this range. Large differences in the extinction coefficients of reduced hemoglobin and oxygenated hemoglobin change the absorbance of light significantly, even when the oxygen saturation changes slightly. A good choice for a wavelength in the red region is 660 nm because of a large difference in the extinction coefficients.

Another issue for the wavelength choice is flatness of the absorption spectra shown in figure 4.2 around the chosen wavelength. Otherwise shifts in the peak wavelength of the LEDs (see section 5.3) will result in a larger error. The absorbance spectra of reduced hemoglobin and oxygenated hemoglobin are relatively flat at 660 and 940 nm (Moyle 1994).

Mannheimer *et al* (1997) have shown that sensors fabricated with 735 and 890 nm emitters read more accurately at low saturations under a variety of conditions, while 660 and 990 nm emitters read more accurately at high saturations.

4.3.2 Absorbance in hemoglobin solutions

The different species of hemoglobin are the main light absorbers in arterial and venous blood. Most of the hemoglobin in human blood is either oxygenated or reduced hemoglobin which determine the functional oxygen saturation SO_2 (equation (4.5)). The concentrations of oxygenated hemoglobin (c_{HbO_2}) and reduced hemoglobin (c_{Hb}) can be expressed as a function of SO_2 as a fraction and the sum of the concentrations c_{HbO_2} and c_{Hb}

$$c_{HbO_2} = SO_2 (c_{HbO_2} + c_{Hb}) \quad (4.8)$$

$$c_{Hb} = (1 - SO_2) (c_{HbO_2} + c_{Hb}). \quad (4.9)$$

According to Beer's law we derive the total absorbance A_t of a solution containing only reduced and oxygenated hemoglobin as absorbing substances from equation (4.4)

$$A_t = \epsilon_{HbO_2}(\lambda) c_{HbO_2} d_{HbO_2} + \epsilon_{Hb}(\lambda) c_{Hb} d_{Hb}. \quad (4.10)$$

Assuming that the optical path length d is the same for the oxygenated hemoglobin (d_{HbO_2}) and reduced hemoglobin (d_{Hb}) and using equations (4.8), (4.9), and (4.10), we derive

$$A_t = [\epsilon_{HbO_2}(\lambda) SO_2 + \epsilon_{Hb}(\lambda)(1 - SO_2)] (c_{Hb} + c_{HbO_2}) d. \quad (4.11)$$

Thus A_t can be expressed for known concentrations of hemoglobin in terms of functional oxygen saturation as a fraction, the extinction coefficients of hemoglobin, and the length of the optical path. Values for the extinction coefficients of adult reduced hemoglobin (ϵ_{Hb}) and adult oxygenated hemoglobin

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(ϵ_{HbO_2}) at the two wavelengths most commonly used in pulse oximetry (660 nm and 940 nm) have been measured by Zijlstra *et al* (1991) (see table 4.1).

Table 4.1 Table of extinction coefficients of reduced and oxygenated hemoglobin in adults at the wavelengths of 660 nm and 940 nm (values from Zijlstra *et al* 1991).

Wavelength, nm	Extinction coefficient, $\text{L mmol}^{-1} \text{cm}^{-1}$	
	Hb	HbO ₂
660	0.81	0.08
940	0.18	0.29

Figure 4.3 shows the characteristics of light absorbance for a sample with a fixed concentration of total functional hemoglobin ($c_{\text{HbO}_2} + c_{\text{Hb}}$) of 1 mmol L^{-1} , a fixed path length d of 1 cm and varying functional oxygen saturations. The two lines shown in figure 4.4 represent the properties for the two most commonly used wavelengths in pulse oximetry (660 nm and 940 nm). The absorbance of light at a wavelength of 940 nm increases with an increased oxygen saturation. At 660 nm the absorbance of light decreases rapidly with an increasing functional oxygen saturation (Pologe 1987).

It is possible to determine the concentrations of hemoglobins in hemoglobin solutions or hemolized blood by using a device such as a spectrophotometer (see section 3.3).

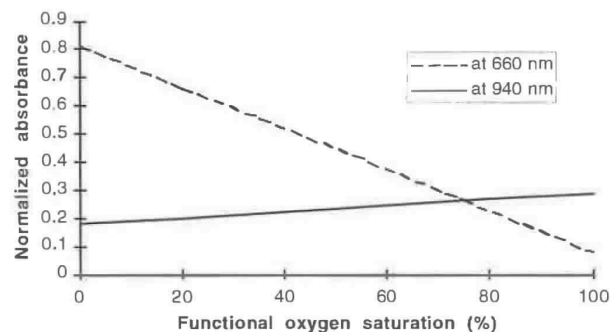


Figure 4.3 Changes in light absorbance in hemoglobin solutions as a function of functional oxygen saturation for the wavelengths used in pulse oximetry. Absorbance decreases rapidly with increasing oxygen saturation at 660 nm (dashed line) but increases slightly with increasing oxygen saturation at 940 nm (solid line).

4.3.3 Pulsation of the blood

Light traveling through biological tissue (e.g. the finger or earlobe) is absorbed by different absorbing substances. Primary absorbers of light in the region of interest are the skin pigmentation, bones, and the arterial and venous blood. Instead of measuring the arterial oxygen saturation of the blood *in vitro* with a sample of arterial blood and a spectrophotometer, or at a wide range of different wavelengths as with the Hewlett-Packard ear oximeter, pulse oximeters take

advantage of *arterial pulsation*. Figure 4.5 shows the amount of absorbed and transmitted light in living tissue as a function of time.

The arteries contain more blood during systole than during diastole, and therefore, their diameter increases due to increased pressure. This effect occurs only in the arteries and arterioles but not in the veins. The absorbance of light in tissues with arteries increases during systole mainly because of the larger amount of absorbing substances (hemoglobin), due to the fact that the optical path length d in the arteries increases. This alternating part of the total absorbance allows us to differentiate between the absorbance due to venous blood, a constant amount of arterial blood, and other nonpulsatile components such as skin pigmentation (dc component of the total absorbance) and the absorbance due to the pulsatile component of the arterial blood (ac component). The alternating part of the light absorbed by the living tissue usually does not exceed 1% to 2% of the constant absorbance of the dc components. The time varying signal of transmitted light is referred to as the plethysmographic (or photoplethysmographic) signal.

The intensity of the light passing through the tissue during diastole is high (I_H). The absorbers that are present during diastole are the DC components. All DC components except the nonpulsating arterial blood are collectively represented by $\epsilon_{DC}(\lambda)$, c_{DC} , and d_{DC} . The diameter of the arterial vessels is minimal (d_{min}) and therefore the absorbance due to arterial hemoglobin is minimal and the amount of transmitted light is high (I_H) and has a peak (see figures 4.4 and 4.5)

$$I_H = I_0 e^{-\epsilon_{DC}(\lambda)c_{DC}d_{DC}} e^{-[\epsilon_{Hb}(\lambda)c_{Hb} + \epsilon_{HbO_2}(\lambda)c_{HbO_2}]d_{min}} \quad (4.12)$$

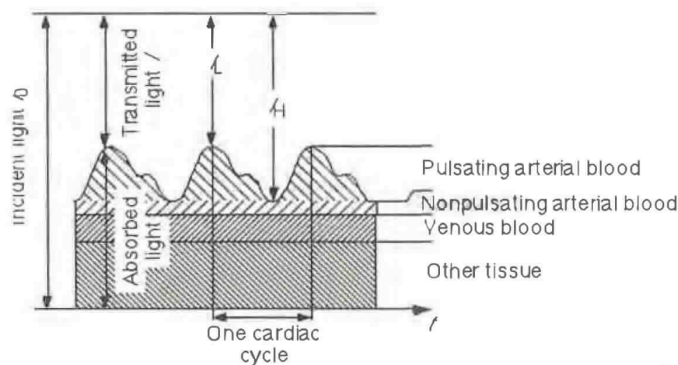


Figure 4.4 Absorbed and transmitted light in living tissue. The amount of absorbed light correlates with the pulsation of arterial blood. A constant amount of light is absorbed by the skin pigmentation, bone, other tissue, venous blood and the nonpulsating part of the arterial blood. More blood is present in the arteries during systole and therefore more light is absorbed. The intensity of the transmitted light varies from I_H (maximum) to I_L (minimum) within one cardiac cycle.

The optical path length in the arteries increases during the systole to d_{max} . The amount of absorbed light reaches a maximum peak and therefore the transmitted light reaches the low peak I_L :

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$$I_L = I_0 e^{-\epsilon_{DC}(\lambda)c_{DC}d_{DC}} e^{-[\epsilon_{Hb}(\lambda)c_{Hb} + \epsilon_{HbO_2}(\lambda)c_{HbO_2}]d_{max}} \quad (4.13)$$

The light intensity I of the light arriving at the photodetector is a function of the diameter d of the arteries and arterioles. During one cardiac cycle this diameter changes from d_{min} to d_{max} . By substituting d with $d_{min} + \Delta d$ we derive the following expression from Beer's law, where I is expressed as a function of I_H and Δd , the part of the diameter that changes from 0 to $d_{max} - d_{min}$ with time

$$I = I_H e^{-[\epsilon_{Hb}(\lambda)c_{Hb} + \epsilon_{HbO_2}(\lambda)c_{HbO_2}]\Delta d} \quad (4.14)$$

Figure 4.5 shows these properties in a simplified model.

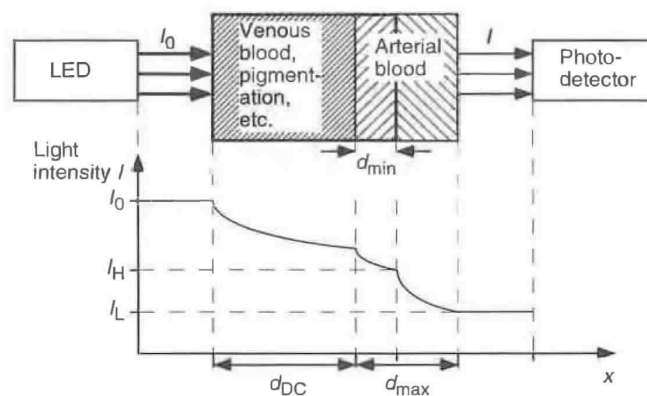


Figure 4.5 Beer's law in pulse oximetry. The DC components of the tissue (e.g. skin pigmentation, bone, venous blood and the nonpulsating part of the arterial blood) absorb a constant amount of the incident light I_0 . The effective optical path length in the DC components without the constant level of arterial blood is represented by d_{DC} . During diastole the optical path length through the arteries has a minimum length of d_{min} and the light intensity at the photodetector is maximal (I_H). The optical path length reaches a maximum d_{max} during systole and the hemoglobin in the arteries absorbs a maximum amount, causing I to decrease to a minimum level of I_L .

4.3.4 *Measurement of pulse oximeters*

The reading of the pulse oximeter S_pO_2 is an estimation of the arterial oxygen saturation S_aO_2 . Measuring at two wavelengths allows us to distinguish the concentrations of only two different absorbers (Hb and HbO_2). But in humans more species of hemoglobin, such as carboxyhemoglobin and methemoglobin, are present. These other hemoglobins absorb light as the functional hemoglobins do and therefore influence our measurements. As long as we do not measure at as many wavelengths as absorbers are present in the blood, we can not determine the concentrations of Hb and HbO_2 and therefore the arterial oxygen saturation correctly (Barker and Tremper 1987).

Due to the fact that Hb and HbO₂ are the main absorbers, the error may be small. Nevertheless, the results of determining either the actual functional or fractional oxygen saturation (see equations (4.5) and (4.7)) of the arterial blood are not exact. This problem is also discussed in sections 10.1.1 and 11.1.1. The oximeter reading becomes less accurate if the concentrations of dyshemoglobins are larger than in normal humans. Section 11.7 deals with the presence of high concentrations of dysfunctional hemoglobins.

4.4 SATURATION VERSUS NORMALIZED RATIO

The arterial oxygen saturation can be derived based on Beer's law as a function of the ratio of absorbances at two wavelengths. Due to nonlinearities in the LEDs, the photodetector, and light absorbance in the tissue, the absorbances have to be normalized in the ratio. This model results in a theoretical calibration curve, but it is not used in practice as will be described in the following sections.

4.4.1 Normalization

The measured light intensities at the different wavelengths have to be *normalized* before they can be compared with each other due to the fact that the light-emitting diodes (LEDs) may emit light with different intensities. The absorbing characteristics of the DC components and the sensitivity of the photodetector differ for the two different wavelengths and the tissue absorption and path length varies widely from patient to patient and with the probe site (de Kock and Tarassenko 1991). The normalized signal I_n is calculated by dividing the transmitted light intensities (the *raw signals*) by their individual maximum peaks ($I_{H,R}$ for the red wavelength and $I_{H,IR}$ for the infrared wavelength). From equation (4.14) we derive

$$I_n = \frac{I}{I_H} = e^{-[\epsilon_{Hb}(\lambda)c_{Hb} + \epsilon_{HbO_2}(\lambda)c_{HbO_2}]\Delta d}, \quad (4.15)$$

This results in normalized signals with the same intensities $I_{H,n}$ during diastole. The normalized signals of the transmitted red and infrared light are independent of the incident light levels and photodetector nonlinearities as shown in figure 4.6. The AC components of the normalized signals represent only changes of transmitted light caused by the pulsation of blood in the arteries and can be compared with each other. They depend on the absorbers present in the arterial blood (ideally Hb and HbO₂) and the actual optical path length d through the volume changing part of the arteries.

4.4.2 Ratio of normalized signals

The absorbance of the light is derived by calculating the natural logarithm of the measured and normalized transmitted light level. Dividing the raw signal by the transmitted light during diastole I_H as in equation (4.15) and calculating the total absorbance then is comparable to calculating the total absorbance only due to the AC components in the pathway. The transmitted light during diastole represents the new nonchanging incident light level and the *ratio* R of these normalized

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absorbances at the red (R) and infrared (IR) wavelengths depends only on the light absorbers present in the arterial blood (see equation (4.3))

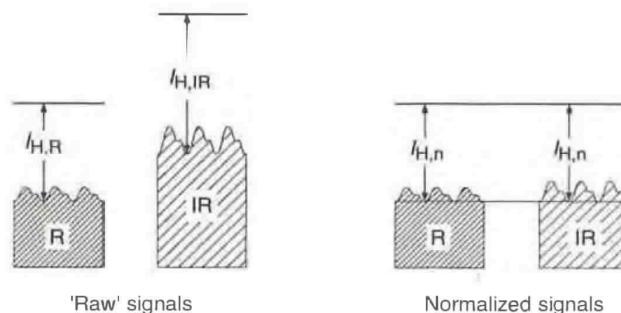


Figure 4.6 The normalization of the signals. The transmitted light from the red LED (R) and from the infrared LED (IR) is divided by its individual DC component. Thus, both normalized light intensities have the same magnitude during diastole. The normalized signals determine the basis for the calculation of the arterial oxygen saturation.

$$R = \frac{A_{t,R}}{A_{t,IR}} = \frac{\ln(I_{L,R} / I_{H,R})}{\ln(I_{L,IR} / I_{H,IR})} \quad (4.16)$$

By using equation (4.15) the ratio can be derived as

$$R = \frac{[(\epsilon_{Hb}(\lambda_R)c_{Hb} + (\epsilon_{HbO_2}(\lambda_R)c_{HbO_2})]\Delta d_R}{[(\epsilon_{Hb}(\lambda_{IR})c_{Hb} + (\epsilon_{HbO_2}(\lambda_{IR})c_{HbO_2})]\Delta d_{IR}} \quad (4.17)$$

Assuming that the optical path lengths d_R for red light and d_{IR} for the infrared light are equal, only the arteries change their diameter, and using equation (4.11)

$$R = \frac{\epsilon_{Hb}(\lambda_R) + [\epsilon_{HbO_2}(\lambda_R) - \epsilon_{Hb}(\lambda_R)]S_aO_2}{\epsilon_{Hb}(\lambda_{IR}) + [\epsilon_{HbO_2}(\lambda_{IR}) - \epsilon_{Hb}(\lambda_{IR})]S_aO_2} \quad (4.18)$$

In this form the ratio R is not a function of the optical path length and can be derived from the arterial oxygen saturation instead of the concentration of the hemoglobins in the blood (see de Kock and Tarassenko 1993).

4.4.3 Theoretic calibration curve

Equation (4.18) can be rewritten in a form where S_aO_2 is a function of the measured and calculated ratio R

$$S_aO_2 = \frac{\epsilon_{Hb}(\lambda_R) - \epsilon_{Hb}(\lambda_{IR})R}{\epsilon_{Hb}(\lambda_R) - \epsilon_{HbO_2}(\lambda_R) + [\epsilon_{HbO_2}(\lambda_{IR}) - \epsilon_{Hb}(\lambda_{IR})]R} \times 100\% \quad (4.19)$$

Therefore, the functional oxygen saturation in arterial blood can be derived theoretically by calculating the ratio R of measured and normalized total light

absorbances in the red and infrared region and using equation (4.19). Figure 4.7 plots this relationship as the *theoretical calibration curve*.

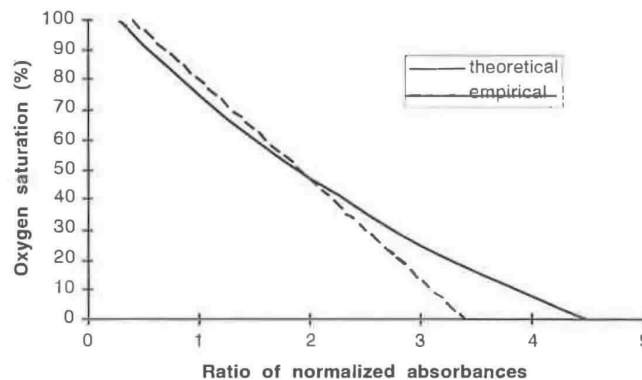


Figure 4.7 Calibration curves for pulse oximeters: the solid line is the theoretical curve by Beer's law and the dashed line is the empirical curve. The difference between these curves is due mainly to light scattering effects. This empirical calibration curve is derived by a second order polynomial.

4.5 VALIDITY OF BEER'S LAW IN PULSE OXIMETRY

Incident light passing through human tissue is not split only into absorbed light and transmitted light as proposed by Beer's law. Some parts of the light are reflected and others are scattered.

Light reflection at the skin surface and light absorbance due to tissue other than the pulsating arterial blood are overcome by using the plethysmographic waveform. However, the skin surface, tissue, muscle, bone and especially blood cause light scattering which increases the absorbance of light (see following section). Blood is a nonhomogeneous liquid, which is capable of nonlinear absorbance of light, e.g. as the concentration of hemoglobins varies (Wukitsch *et al* 1988).

The variation in light absorbance is not entirely due to the increased optical path length during systole. If the change in diameter were the only reason, the variation would be much less. The reason is a change in the axis of the red blood cells, which changes their absorbance as well. Red blood cells have the shape of a biconcave disk. Their major diameter is aligned parallel to the direction of blood flow during diastole and aligns perpendicular to the direction of flow during systole. Therefore, the optical path length is larger during systole and increases light absorbance. Even the light reflectance changes with the axis of the red blood cells, which is important for the use of reflectance probes. As a result of these properties, the absorbance and reflectance of blood in motion varies within the cardiac cycle and with the velocity of blood flow (Moyle 1994).

4.6 LIGHT SCATTERING

The results of oximetry measurements with whole blood differ from the results of the theory based on Beer's law. A physical phenomenon called *light scattering* highly increases the absorbance of light. Nevertheless, pulse oximeters read the arterial oxygen saturation of the blood accurately enough for clinical use under normal circumstances. This is due to the fact that most of the commercial pulse oximeters use a calibration curve based on empirical data, because modeling the problem of light scattering mathematically for different conditions is very complex. Several approaches have been made to create models which describe the real process within certain limits of accuracy.

4.6.1 *Light absorbance in whole blood*

Unfortunately Beer's law does not apply for whole blood. The absorbance of light is not simply proportional to the concentration of hemoglobin or to the length of the optical path. Beer's law assumes no light scattering, which is not true in whole blood, besides the fact that the LEDs do not emit monochromatic light.

Shymada and Yoshida (1984) verified that the influence of multiple scattering can not be overcome by subtracting the DC level as had been expected. Kramer *et al* (1951) stated that the absorbance of light due to oxyhemoglobin and reduced hemoglobin is increased in whole blood compared to hemolyzed blood by factors of the order of five.

The reasons for the increased absorbance are mainly *scattering* and *multiple scattering*. Light scattering causes the deviation of a light beam from its initial direction. It occurs when light is refracted by an object of a size similar to the magnitude of the wavelength of the light and a change in the index of refraction at the interface of this object. The wavelengths of red and infrared light do have the same order of magnitude as the geometric dimensions of red blood cells (approximately 7 μm in diameter). The discontinuity in the index of refraction at the interface between plasma and red blood cells and the great proportion of red blood cells in blood yield a highly light scattering medium. Light that is scattered once will likely be scattered again by cells and therefore multiple scattering occurs (Steinke and Shepherd 1986). Multiple scattering increases the optical path length and therefore increases the absorbance.

The intensity of the light scattered by the tissue depends on such factors as the red blood cell concentration in the blood; on the size, shape, orientation, and index of refraction of the scattering particles; on the tissue thickness; and on the aperture cone of the detector (Fine and Weinreb 1995). The thickness of the tissue, the distance between the LED and the photodiode, and the concentration of hemoglobin will vary from patient to patient and the shape and orientation of the red blood cells is irregular. Thus it is difficult to develop a physical model which can be used under different circumstances.

4.6.2 *Models for light absorbance including scattering*

It would be very useful to find a relationship between S_aO_2 and the ratio R of normalized absorbances for whole blood instead of only for hemoglobin solutions. An accurate scattering theory for whole blood could replace the

empirical calibration curves used for the S_pO_2 readings. A few attempts are described below.

4.6.2.1 Twersky's multiple scattering theory. Twersky (1962, 1970a,b) has developed an analytical theory to describe the scattering of light by large, low-refracting, and absorbing particles. It is based on electromagnetic field theory and uses statistical averages to expand the theory for scattering and absorbing valid for a single particle, to find a formulation valid for multiple scattering (de Kock and Tarassenko 1993).

The total absorbance of whole blood can be expressed as the sum of absorbance as described by Beer's law and a second term representing the attenuation of light due to scattering. These two processes can be treated as independent processes. The intensity of scattering depends on variables such as those mentioned in section 4.6.1. The theory can be adapted for a special setting and will provide accurate results, but once the physiological conditions change, recalibration is required (Fine and Weinreb 1995). Hitachi, Ltd uses Twersky's approach in one of their US patents (Ito *et al* 1993).

4.6.2.2 Comparison of different models. Steinke and Sheperd (1986) compared Twersky's theory of radiation scattering and photon diffusion equations. They found Twersky's original equation to give the best fit for the measured data.

Marble *et al* (1994) found the three dimensional photon diffusion theory to be useful for modeling tissue optics although the pulse oximeter system violates many of the requirements of the model. However, they came to the conclusion that this theory can not replace clinical calibration studies.

De Kock and Tarassenko (1993) also found Twersky's theory to give the best fit to the experimental data. They compared results of this model with the photon diffusion theory and the Kubelka-Munk theory.

4.6.3 Influence of scattering on pulse oximeter readings

Although the assumptions of Beer's law are violated in pulse oximetry, the actual readings of the devices show a good correlation between the measurement and the actual arterial oxygen saturation.

Steinke and Sheperd (1986) found that the scattering effects of the light passing through whole blood depend on the wavelength of the light and the oxygen saturation. The relationship between oxygen saturation and total scattering effects (absorbance due to hemoglobin plus multiple scattering) is approximately linear and so scattering does not influence the linearity of the pulse oximeter in a negative way. In contrast, the total absorbance has a larger slope than that due only to the absorbance of hemoglobin following Beer's law. Therefore, light scattering increases the sensitivity of the whole blood oximeter.

Fine and Weinreb (1993, 1995) demonstrate that the ratio of total absorbances is a function of the effective blood layer thickness and the concentration of hemoglobin. Therefore physiological factors such as temperature or peripheral vasoconstriction reduce the accuracy of saturation readings. The error increases as the level of arterial oxygen saturation decreases. This is dangerous because the clinician has to question the readings of the oxygen saturation when it is most critical for the patient.

4.6.4 Calibration curves used for pulse oximeters

Commercial pulse oximeters are calibrated from *in vitro* data (see section 10.1). A large set of data obtained in clinical studies is collected containing information about the ratio R of the absorbances calculated by the pulse oximeter and the actual arterial oxygen saturation S_aO_2 measured by a very accurate method such as the CO-oximeter (see section 3.3). Lookup tables or equations are used to find the relationship of these two variables for a pulse oximeter reading.

To relate the measured values of the ratio R to the reading of the pulse oximeter, the equation of the theoretical calibration curve based on Beer's law can be modified as Mendelson and Kent (1989) described

$$S_pO_2 = \frac{k_1 - k_2 R}{k_3 - k_4 R} \quad (4.20)$$

In this equation the extinction coefficients from equation (4.19) are replaced by constants k_i . These constants are determined by clinical studies to give the curve a best fit to the *in vitro* measured data. Another approach for a mathematical representation is the use of a polynomial such as found for example in the Ohmeda 3700 and Radiometer OX100 pulse oximeters (Fine and Weinreb 1995)

$$S_pO_2 = k_1 + k_2 R + k_3 R^2 \quad (4.21)$$

Figure 4.7 provides an example of a calibration curve used in pulse oximeters in comparison to the theoretical calibration curve.

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INSTRUCTIONAL OBJECTIVES




- 4.1 Describe the properties and limitations of Beer's law.
- 4.2 Describe different species of hemoglobin and their effect on the oxygenation of blood.
- 4.3 Describe the functional and the fractional hemoglobin saturation and their difference.
- 4.4 Describe the properties and assumptions of the spectrophotometric method to determine oxygen saturation in hemoglobin solutions.
- 4.5 Describe the principles of pulse oximetry and what a pulse oximeter measures.
- 4.6 Describe why and how a pulse oximeter measures the absorbance in the arterial blood only.
- 4.7 Describe the normalization of the signals and the reasons for this normalization.
- 4.8 Explain how and why the ratio of the normalized signals is calculated.
- 4.9 Explain errors in the spectrophotometric method when used for whole blood samples.
- 4.10 Describe the different physical phenomena occurring when light travels through tissue and blood.
- 4.11 Describe what light scattering is and where it occurs in pulse oximetry.
- 4.12 Describe the influence of light scattering on the accuracy of a pulse oximeter.

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Apple Watch Series 6 delivers breakthrough wellness and fitness capabilities - Apple

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PRESS RELEASE

September 15, 2020

Apple Watch Series 6 delivers breakthrough wellness and fitness capabilities



Featuring a Blood Oxygen sensor and app, new case finishes, and watchOS 7

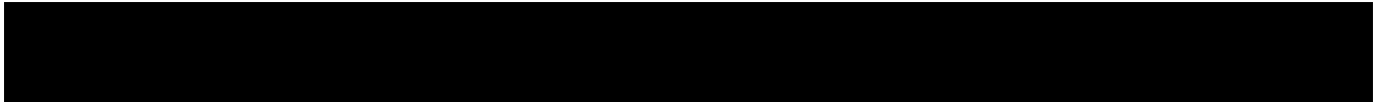


Introducing Apple Watch Series 6, featuring a revolutionary Blood Oxygen sensor and app.



Cupertino, California — Apple today announced [Apple Watch Series 6](#), introducing a revolutionary Blood Oxygen feature that offers users even more insight into their overall wellness. Apple Watch Series 6 delivers many notable hardware improvements, including a faster S6 System in Package (SiP) and next-generation always-on altimeter, along with its most colorful lineup yet, featuring a beautiful palette of new case finishes and bands. watchOS 7 brings Family Setup, sleep tracking, automatic handwashing detection, new workout types, and the ability to curate and share watch faces, encouraging customers to be more active, stay connected, and better manage their health in new ways.

"Apple Watch Series 6 completely redefines what a watch can do," said Jeff Williams, Apple's chief operating officer. "With powerful new features, including a Blood Oxygen sensor and app,¹ Apple Watch becomes even more indispensable by providing further insight into overall well-being."



Apple Watch Series 6 offers its most colorful collection yet.



Blood Oxygen Sensor and App

Apple Watch Series 6 expands the health capabilities of previous Apple Watch models with a new feature that conveniently measures the oxygen saturation of the user's blood, so they can better understand their overall fitness and wellness. Oxygen saturation, or SpO₂, represents the percentage of oxygen being carried by red blood cells from the lungs to the rest of the body, and indicates how well this oxygenated blood is being delivered throughout the body.

To compensate for natural variations in the skin and improve accuracy, the Blood Oxygen sensor employs four clusters of green, red, and infrared LEDs, along with the four photodiodes on the back crystal of Apple Watch, to measure light reflected back from blood. Apple Watch then uses an advanced custom algorithm built into the Blood Oxygen app, which is designed to measure blood oxygen between 70 percent and 100 percent. On-demand measurements can be taken while the user is still, and periodic background measurements occur when they are inactive, including during sleep. All data will be visible in the Health app, and the user will be able to track trends over time to see how their blood oxygen level changes.

The new Blood Oxygen sensor and app conveniently measure the oxygen saturation of blood so users can better understand their overall fitness and wellness.



Apple is joining forces with researchers to conduct three health studies that include using Apple Watch to explore how blood oxygen levels can be used in future health applications. This year, Apple will collaborate with the University of California, Irvine, and Anthem to examine how longitudinal measurements of blood oxygen and other physiological signals can help manage and control asthma.

Separately, Apple will work closely with investigators at the Ted Rogers Centre for Heart Research and the Peter Munk Cardiac Centre at the University Health Network, one of the largest health research organizations in North America, to better understand how blood oxygen measurements and other Apple Watch metrics can help with management of heart failure. Finally, investigators with the Seattle Flu Study at the Brotman Baty Institute for Precision Medicine and faculty from the University of Washington School of Medicine will seek to learn how signals from apps on Apple Watch, such as Heart Rate and Blood Oxygen, could serve as early signs of respiratory conditions like influenza and COVID-19.



The Blood Oxygen sensor employs LEDs, along with photodiodes on the back crystal of Apple Watch Series 6.



Design and Performance

Apple Watch Series 6 improves performance through redesigned hardware that packs even more features and power into the same impressively small design. Using a new dual-core processor based on A13 Bionic in iPhone 11, the upgraded S6 SiP runs up to 20 percent faster, allowing apps to also launch 20 percent faster, while maintaining the same all-day 18-hour battery life.² Additionally, Apple Watch Series 6 features the U1 chip and Ultra Wideband antennas,³ which will enable short-range wireless location to support new experiences, such as next-generation digital car keys. Apple Watch Series 6 offers faster charging, completing a full charge in under 1.5 hours, and improved battery life for tracking certain workouts, such as indoor and outdoor runs.

An enhanced Always-On Retina display on Apple Watch Series 6 is up to 2.5 times brighter than Apple Watch Series 5 outdoors when the user's wrist is down, making it much easier to see a watch face in bright sunlight. When their wrist is down, the user can also now access Notification Center and Control Center, tap on complications, and swipe to change faces without having to wake their watch screen.



The Always-On Retina display is 2.5 times brighter while the user's wrist is down.



Always-On Altimeter

The always-on altimeter provides real-time elevation all day long by using a new, more power-efficient barometric altimeter, along with GPS and nearby Wi-Fi networks. This feature allows for the detection of small elevation changes above ground level, up and down to the measurement of 1 foot, and can be shown as a new watch face complication or workout metric.



The always-on altimeter on Apple Watch Series 6 provides real-time elevation all day long.



Apple Watch Collection

This fall, customers have more choices than ever with stunning new cases and bands to suit every style preference. For the first time, a new blue color joins the silver, space gray, and gold aluminum case options, along with a (PRODUCT)RED Apple Watch with exclusive matching bright red bands. Stainless steel models are now available in graphite — a rich gray-black hue with a striking high-shine finish — and an updated classic yellow gold color. Apple Watch Edition is available in natural and space black titanium.



Apple Watch Series 6 with the distinct Braided Solo Loop and blue aluminum case.



Three all-new band styles offer customers innovative options that provide a tailored and comfortable fit without traditional clasps or buckles. In an industry first, the ultralight Solo Loop introduces a continuous and stretchable band design that comes in two materials: soft silicone and braided yarn. A special UV treatment process used on the soft silicone of the Solo Loop creates a smooth, silky finish, while a precision-braiding machine interweaves the 16,000 polyester yarn filaments, made of 100 percent recycled material, with ultrathin silicone threads, giving unique stretchability and a distinct look to the Braided Solo Loop. To ensure the best fit, a new sizing system offers nine available lengths for the Solo Loop styles. The first-of-its-kind Leather Link wraps elegantly around the wrist, effortlessly attaching on the other side with flexible molded magnets.



Apple Watch Nike now comes with new colors for the Nike Sport Band and Nike Sport Loop.



Apple Watch Nike now comes with new colors for the Nike Sport Band and Nike Sport Loop, and a new Nike Compact watch face allows for multiple Nike Run Club complications. Apple Watch Hermès offers stainless steel cases in silver or space black paired with Single or Double Tour styles in an assortment of vibrant new colors. The fall collection also unveils the Hermès Attelage Single Tour and slimmer Attelage Double Tour bands, which feature a refined connection to the case that reflects the brand's equestrian heritage, and a new Hermès Circulaire watch face that offers increased options for complications.



Apple Watch Hermès introduces the Hermès Attelage Single Tour and slimmer Attelage Double Tour bands, along with new colors of classic band styles.



watchOS 7

With watchOS 7, customers can take personalization to the next level with seven new watch face options, including Stripes, Chronograph Pro, GMT, and Artist, while curating, discovering, and sharing new watch face configurations with others. New health and fitness features, including low-range VO2 Max, sleep tracking, automatic

handwashing detection, and new workout types, can help users better understand overall well-being. Conveniently accessible on the wrist, Maps includes cycling directions and Siri offers language translation.



watchOS 7 features seven new watch face options — including Chronograph Pro and GMT — plus new watch face configurations users can curate, discover, and share with others.



Family Setup and Optimized Features for the Entire Family

Family Setup⁴ in watchOS 7 extends Apple Watch to the entire family by allowing kids and older family members of the household who do not have an iPhone to benefit from the connectivity, safety, and fitness features of Apple Watch. Kids can take advantage of communication and personalization capabilities, access Emergency SOS at any time, enjoy an Activity rings experience that has been optimized just for them, and utilize a new mode called Schooltime, which can help them stay focused and attentive while learning at home or in the classroom.

watchOS 7 also offers optimized features for older adults, starting with a simplified onboarding and configuration process, along with a refreshed X-Large face that shows the time and a rich complication at a glance. Older adults can also benefit

from a new Health Checklist in the Health app on iPhone, which offers the ability to track whether health features like fall detection have been enabled in one centralized view.

Pricing and Availability

- Apple Watch Series 6 (GPS) starts at **\$399** and Apple Watch Series 6 (GPS + Cellular) starts at **\$499**.
- Apple Watch Series 6 (GPS) is available to order today from apple.com and in the Apple Store app, with availability beginning Friday, September 18, in the *US*, *Puerto Rico*, and 27 other countries and regions.
- Apple Watch Series 6 (GPS + Cellular) is available to order today from apple.com and in the Apple Store app, with availability beginning Friday, September 18, in the *US*, *Puerto Rico*, and 21 other countries and regions. For carrier availability, visit apple.com/watch/cellular.
- Apple Watch Nike is available to order today from apple.com and in the Apple Store app, with availability beginning Friday, September 18, in the *US*, *Puerto Rico*, and more than 27 other countries and regions. For more information, visit apple.com/apple-watch-nike or nike.com/applewatch.
- Apple Watch Hermès is available to order today from apple.com and in the Apple Store app, with availability beginning Friday, September 18, in the *US* and more than 14 other countries and regions. For more information, visit apple.com/apple-watch-hermes or hermes.com/applewatchhermes.
- New Apple Watch bands are available to order today from apple.com and in the Apple Store app, with availability beginning Friday, September 18. Solo Loop and Braided Solo Loop in (PRODUCT)RED will be available in late October. Solo Loop and Braided Solo Loop are compatible with Apple Watch Series 4 and later.
- watchOS 7 will be available for Apple Watch Series 3 and later on September 16, and requires iPhone 6s or later running iOS 14. Not all features are available on all devices.
- When customers buy directly from Apple, Apple Watch Studio gives them the exclusive opportunity to pick their preferred case and band combination to create a look that is uniquely their own.
- Customers looking for convenient, contactless service are able to find many of the same shopping and support services from apple.com. Customers can chat with an Apple Specialist and get shopping help, choose monthly financing options, trade in eligible devices, and get Genius support and no-contact delivery. In-store pickup is also available. Customers are encouraged to check apple.com/retail for more information on the health and safety measures in place, and the services available at their local store.
- Customers in the US can trade in their eligible device for an Apple Gift Card or credit toward their purchase. If the device is not eligible for credit, Apple will recycle it for free.⁵
- Three months of Apple Fitness+ are included for customers who purchase Apple Watch Series 3 or later starting September 15, 2020. This extended trial is available for a limited time.⁶
- Customers in the US who buy directly from Apple can choose Apple Card Monthly installments to pay for their Apple Watch over 24 months, interest-free, and get 3 percent Daily Cash back all upfront. Customers who choose to pay in full with their Apple Card also get 3 percent Daily Cash back.
- Customers can extend their limited warranty with AppleCare+ and get accidental damage coverage and 24/7 priority access to technical support.

- Customers who buy Apple Watch directly from Apple can enjoy a free Online Personal Session with an Apple Specialist to help them explore and discover all the amazing things they can do with their new Apple Watch.⁷
- In line with Apple's commitment to the environment, there are industry-leading amounts of recycled content in Apple Watch Series 6, with 100 percent recycled rare earth elements in the Taptic Engine, nearly 100 percent recycled tungsten throughout the product, and a 100 percent recycled case on aluminum models. Apple is also helping the environment by removing the AC adapter that could become electronic waste from Apple Watch Series 6 packaging, and helping its Apple Watch manufacturing partners transition to renewable energy.

To see all of the latest announcements and photos from today's keynote event, check out the [wrap-up on Apple Newsroom](#).

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Images of Apple Watch Series 6

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Apple revolutionized personal technology with the introduction of the Macintosh in 1984. Today, Apple leads the world in innovation with iPhone, iPad, Mac, Apple Watch, and Apple TV. Apple's five software platforms — iOS, iPadOS, macOS, watchOS, and tvOS — provide seamless experiences across all Apple devices and empower people with breakthrough services including the App Store, Apple Music, Apple Pay, and iCloud. Apple's more than 100,000 employees are dedicated to making the best products on earth, and to leaving the world better than we found it.

1. Blood Oxygen app measurements are not intended for medical use, including self-diagnosis or consultation with a doctor, and are only designed for general fitness and wellness purposes.
2. Battery life varies by use.
3. Not available in all countries.
4. Requires cellular models of Apple Watch Series 4 or later, or Apple Watch SE.
5. Trade-in values vary based on the condition, year, and configuration of your trade-in device, and may also vary between online and in-store trade-in. You must be at least 18 years old. Offer may not be available in all countries. In-store trade-in requires presentation of a valid government-issued photo ID (local law may require saving this information). Additional terms from Apple or Apple's trade-in partners may apply.
6. \$9.99 per month or \$79.99 per year after free trial. No commitment. Plan automatically renews until cancelled.
7. In most countries.

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RX-0411



US007620212B1

(12) **United States Patent**
Allen et al.

(10) **Patent No.:** **US 7,620,212 B1**
(45) **Date of Patent:** **Nov. 17, 2009**

(54) **ELECTRO-OPTICAL SENSOR**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 963 days.

(21) Appl. No.: **10/640,503**

(22) Filed: **Aug. 12, 2003**

Related U.S. Application Data

(60) Provisional application No. 60/460,247, filed on Apr. 4, 2003, provisional application No. 60/403,453, filed on Aug. 13, 2002, provisional application No. 60/403,452, filed on Aug. 13, 2002, provisional application No. 60/403,593, filed on Aug. 13, 2002, provisional application No. 60/403,461, filed on Aug. 13, 2002, provisional application No. 60/403,449, filed on Aug. 13, 2002.

(51) **Int. Cl.**
G06K 9/00 (2006.01)

(52) **U.S. Cl.** **382/115**; 340/5.53; 340/5.83; 713/186

(58) **Field of Classification Search** 382/115-127; 340/5.1, 5.2, 5.52, 5.53, 5.8-5.86; 902/3; 356/71; 713/186

See application file for complete search history.

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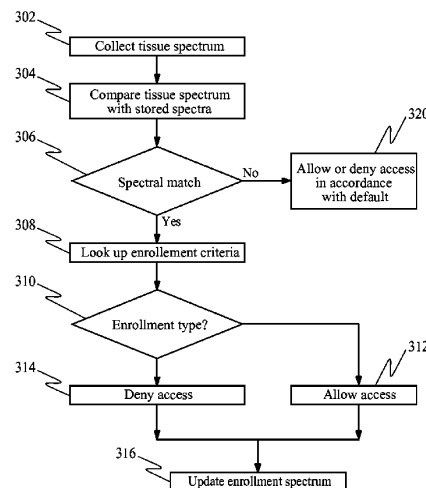
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(57) **ABSTRACT**

Methods and systems are provided that extend the functionality of electro-optical sensors. A device has a multiple light sources, a light detector, and a processor configured to operate the light sources and the light detector to perform distinct functions. At least one of the distinct functions includes a biometric identification function in which light is propagated from the plurality of light sources through presented material. The propagated light is received with the light detector, with the presented material being identified from the received light. Another of the distinct functions includes a nonidentification function performed with the light sources and the light detector.

19 Claims, 16 Drawing Sheets



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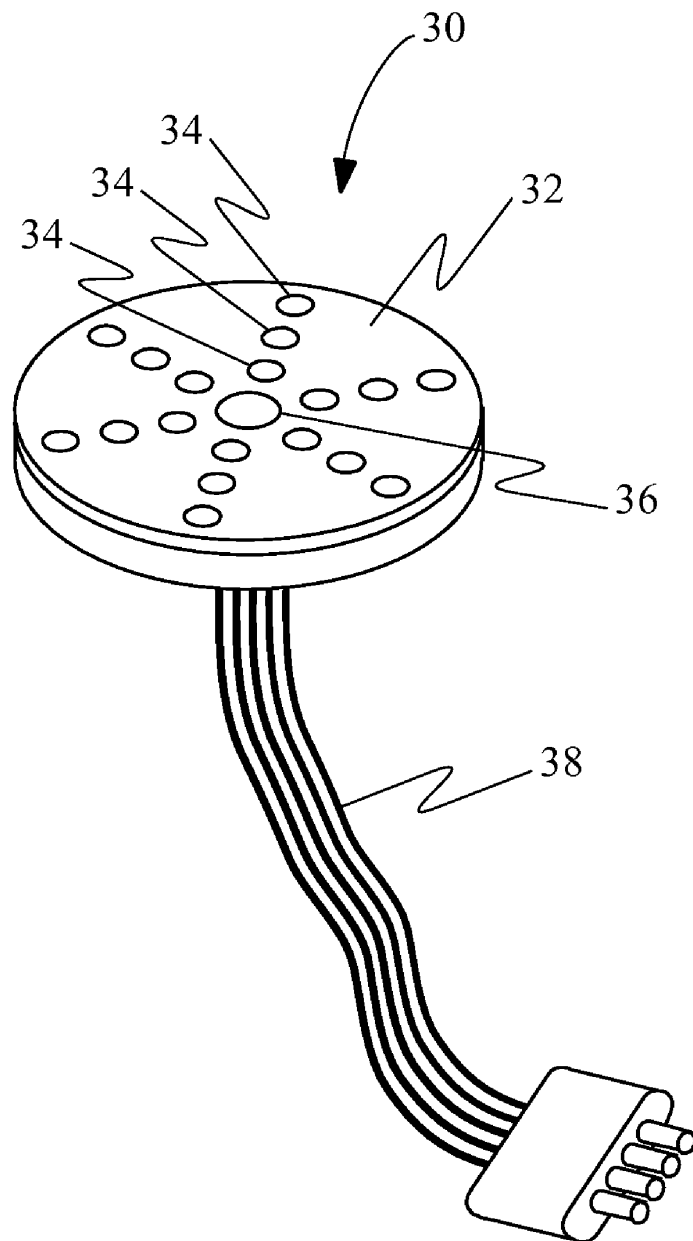


FIG. 1

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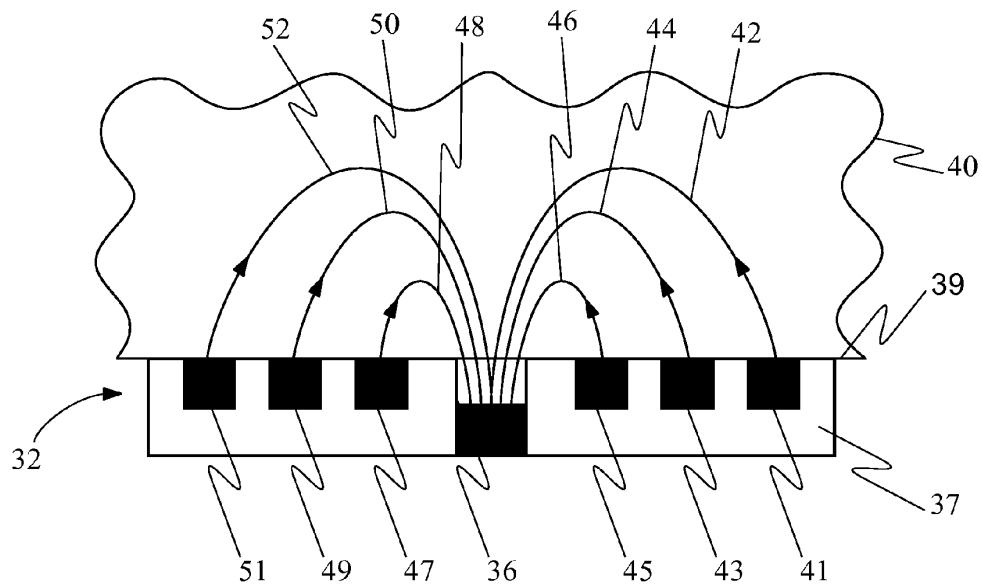


FIG. 2

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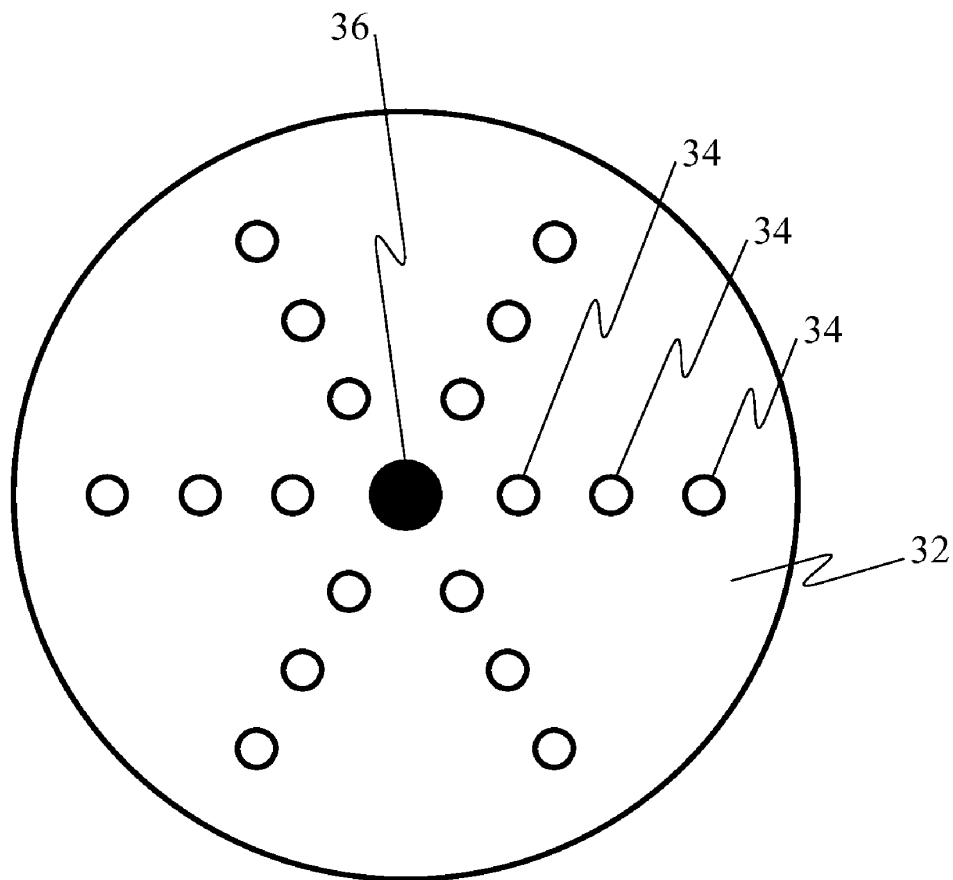


FIG. 3

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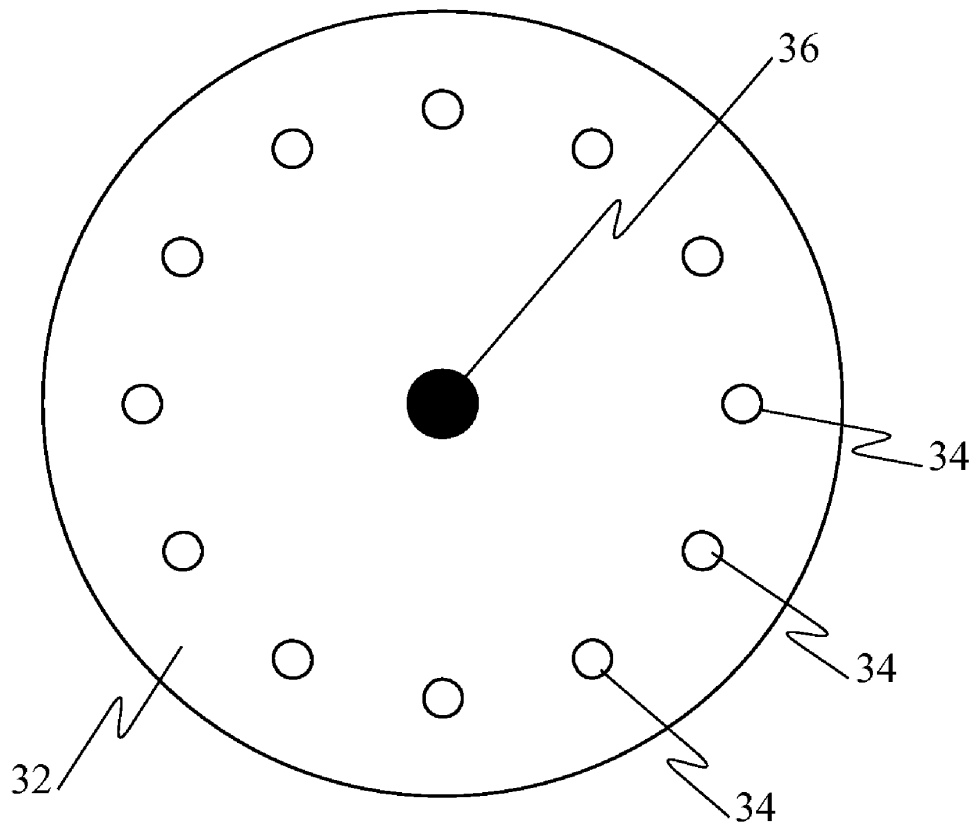


FIG. 4

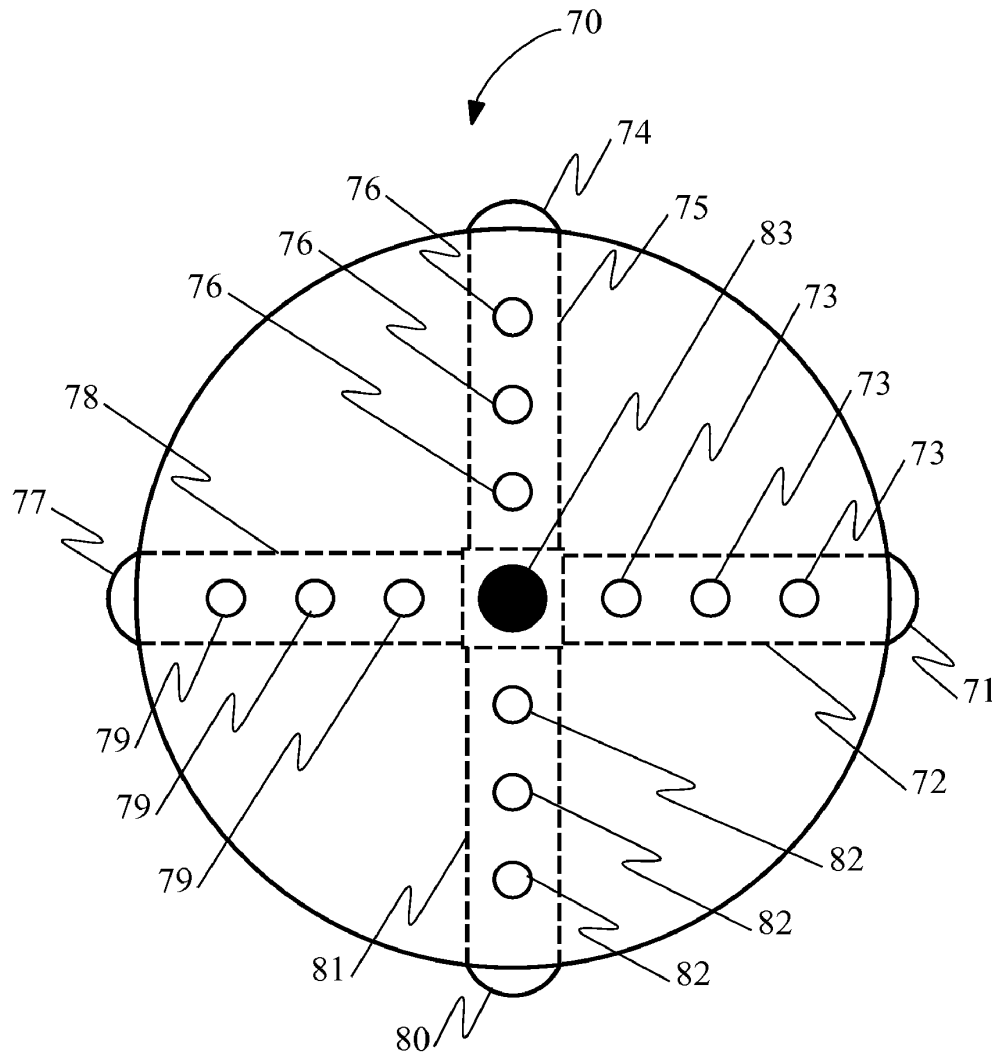


FIG. 5

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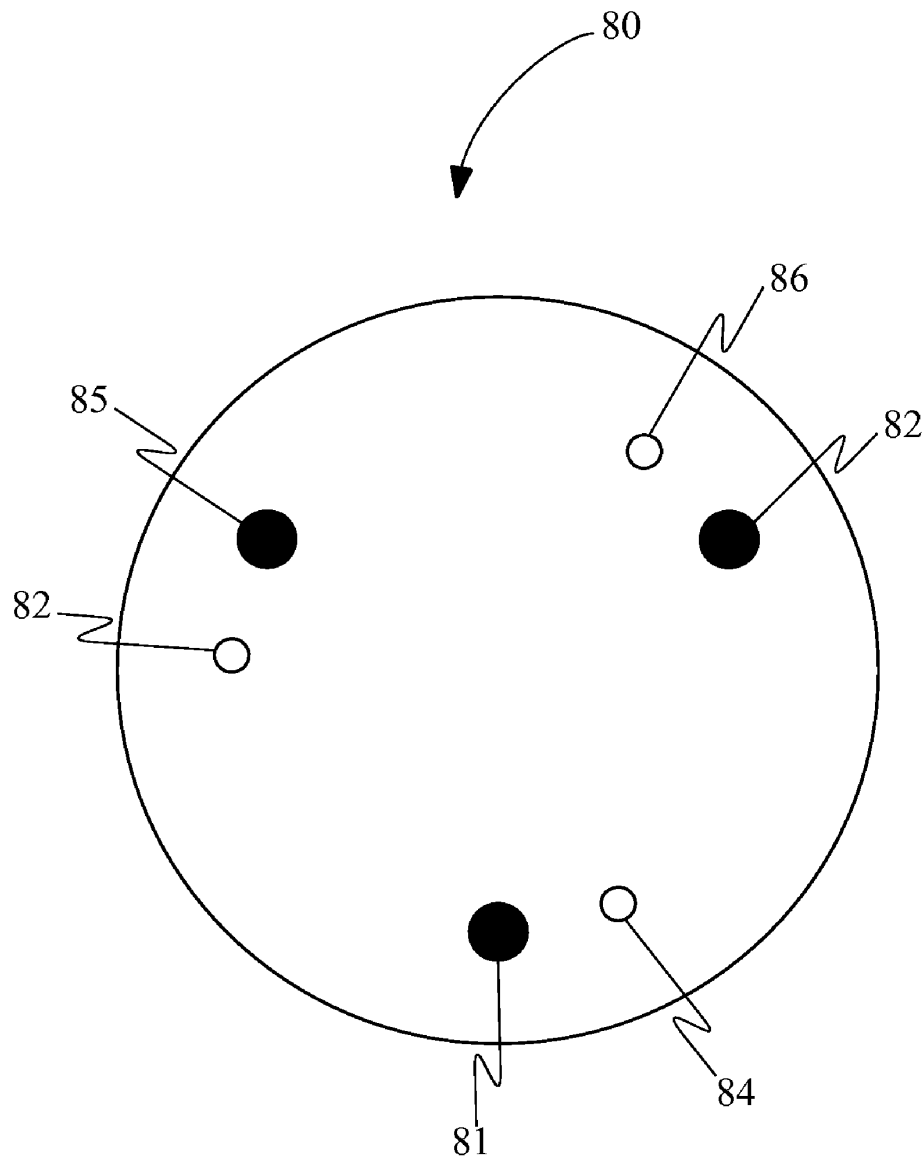


FIG. 6

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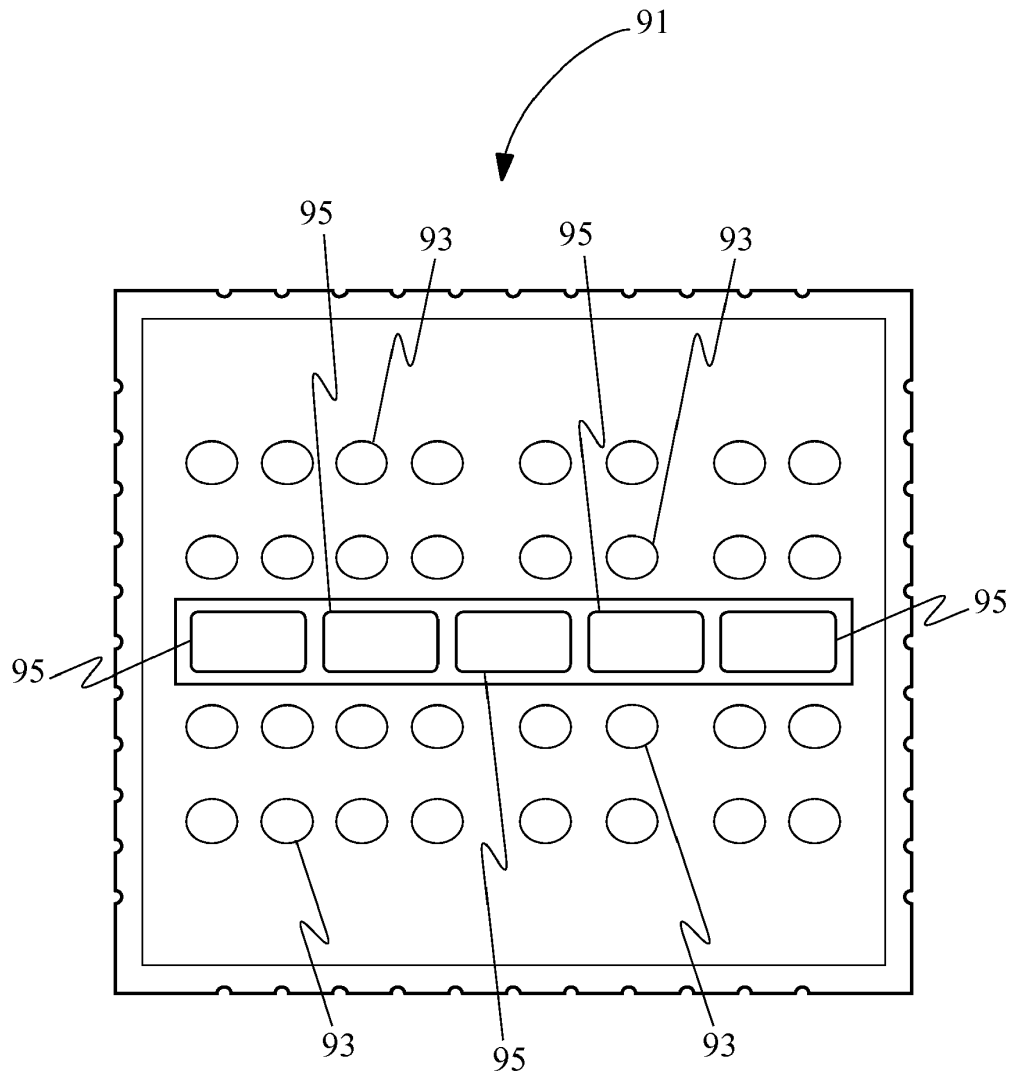


FIG. 7A

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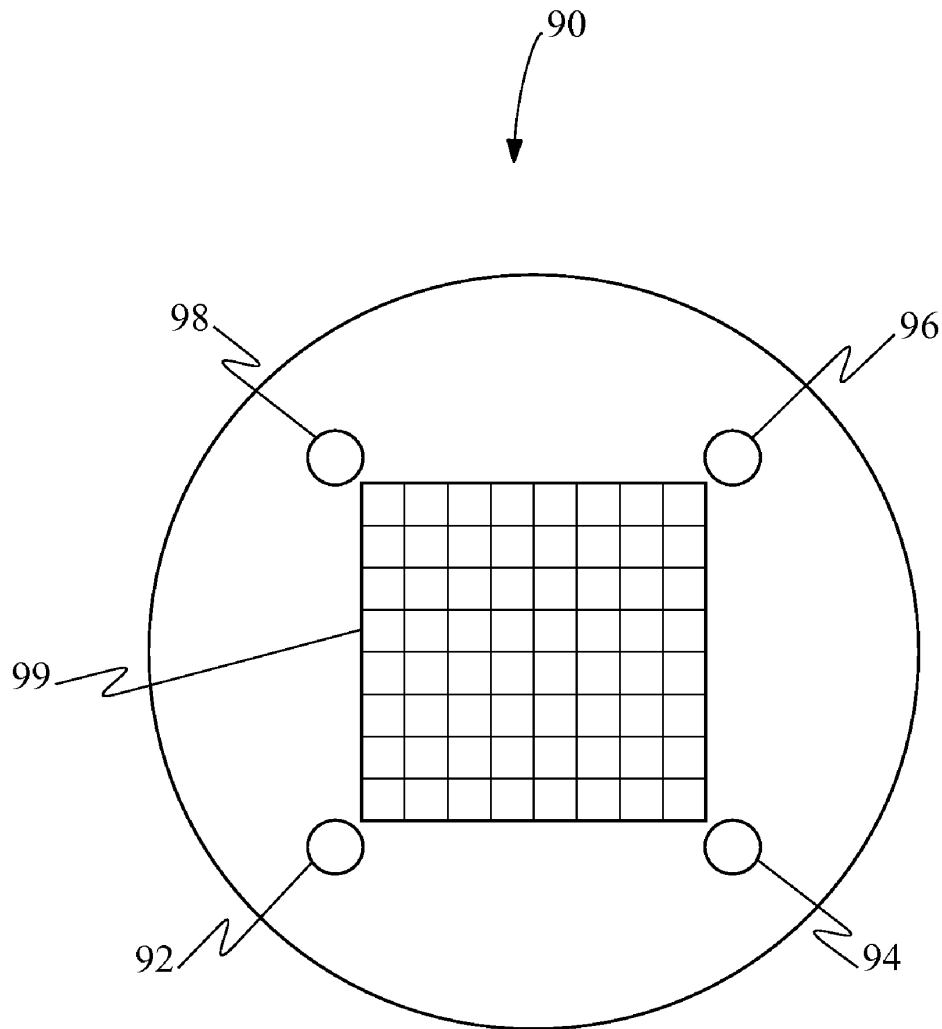


FIG. 7B

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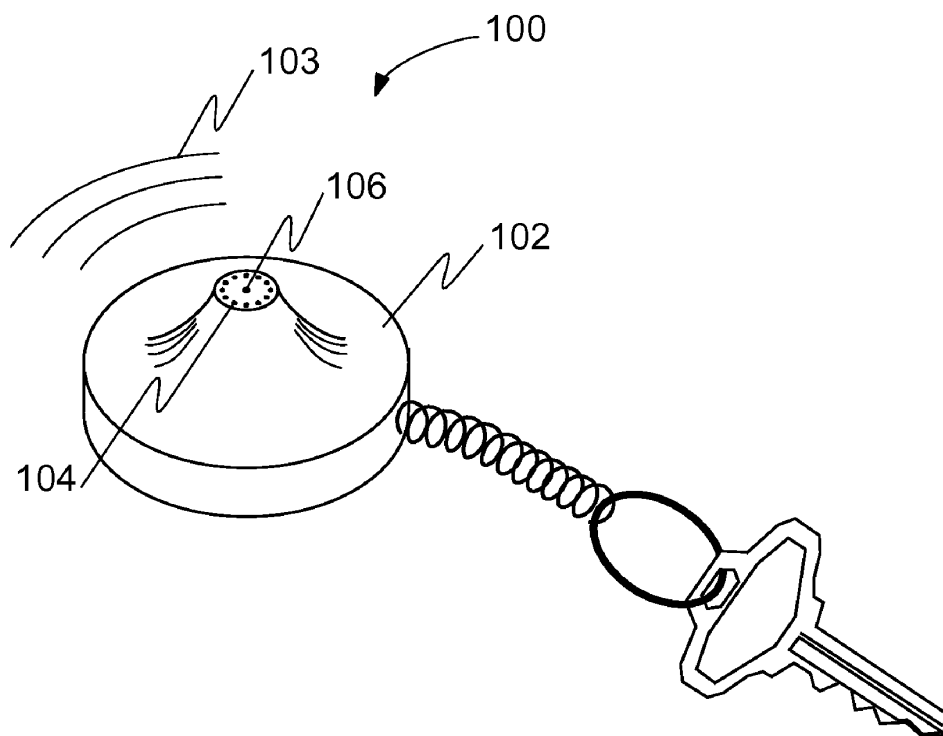


FIG. 8A

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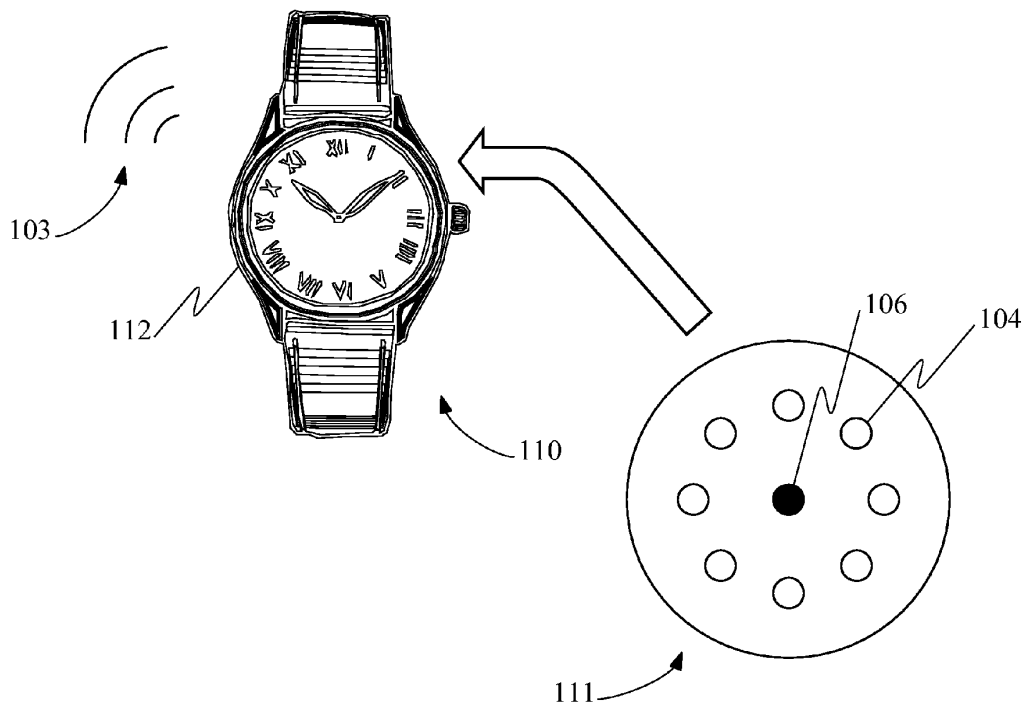


FIG. 8B

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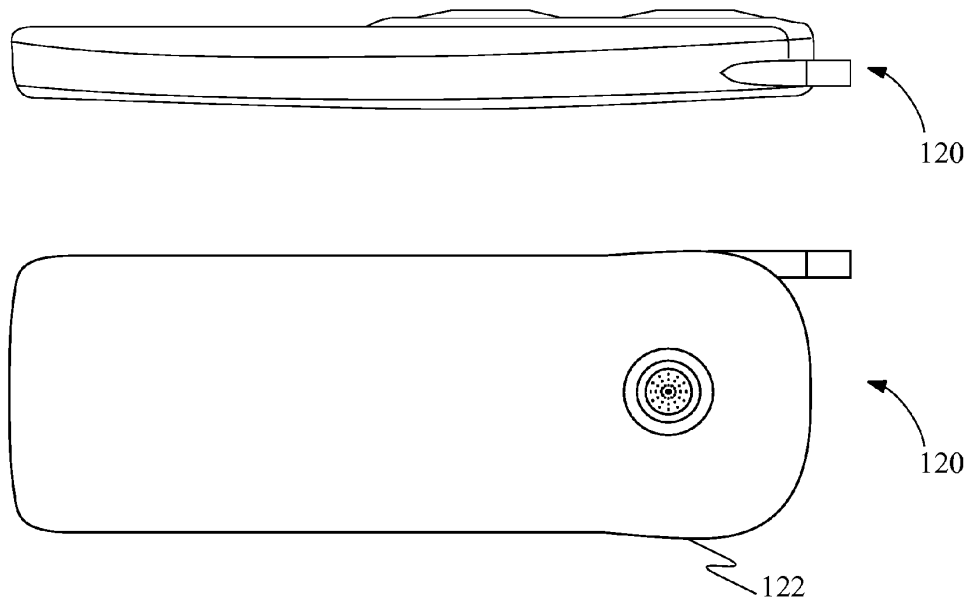


FIG. 8C

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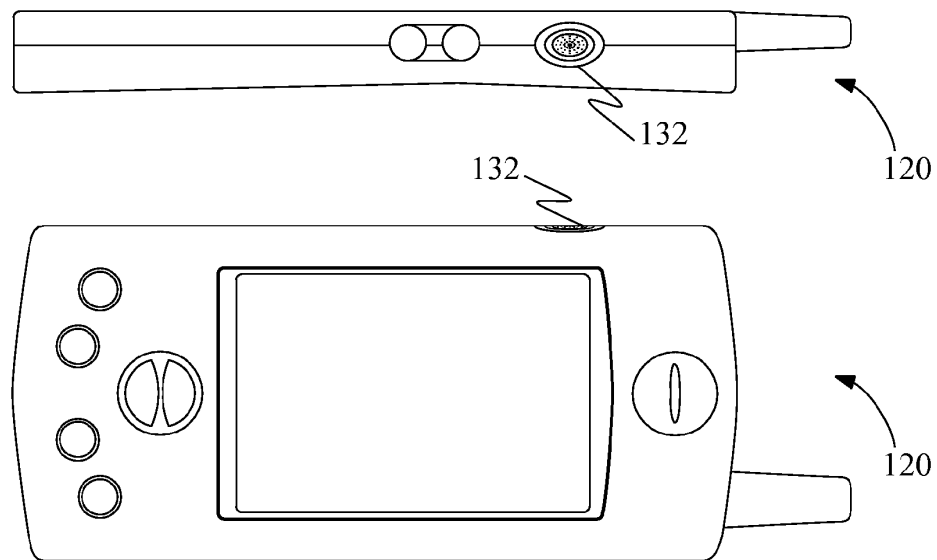


FIG. 8D

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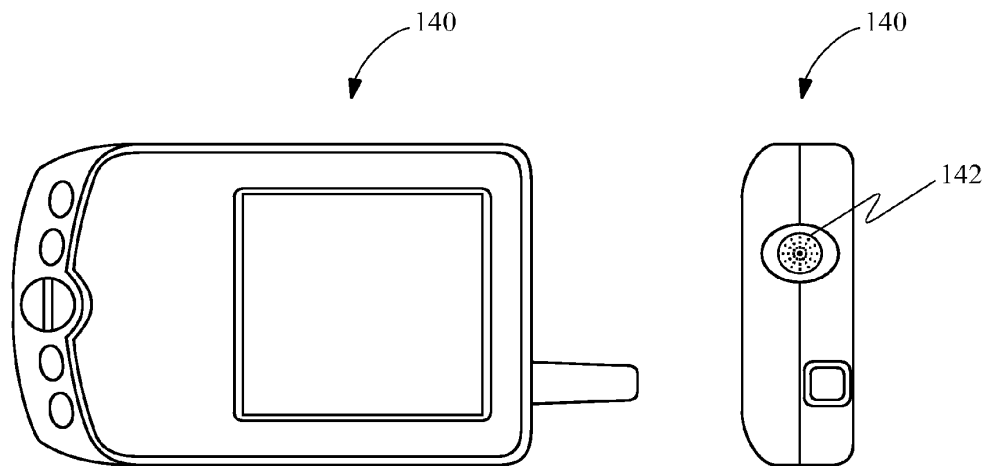


FIG. 8E

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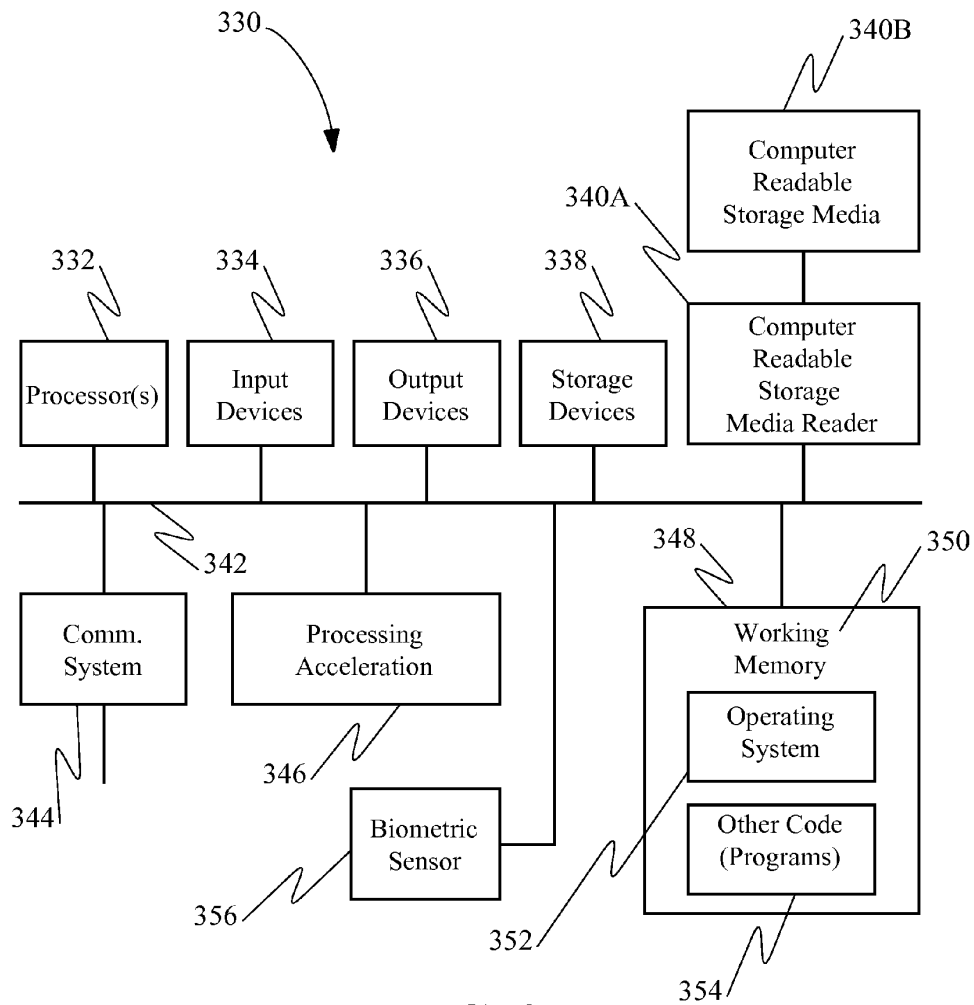


FIG. 9

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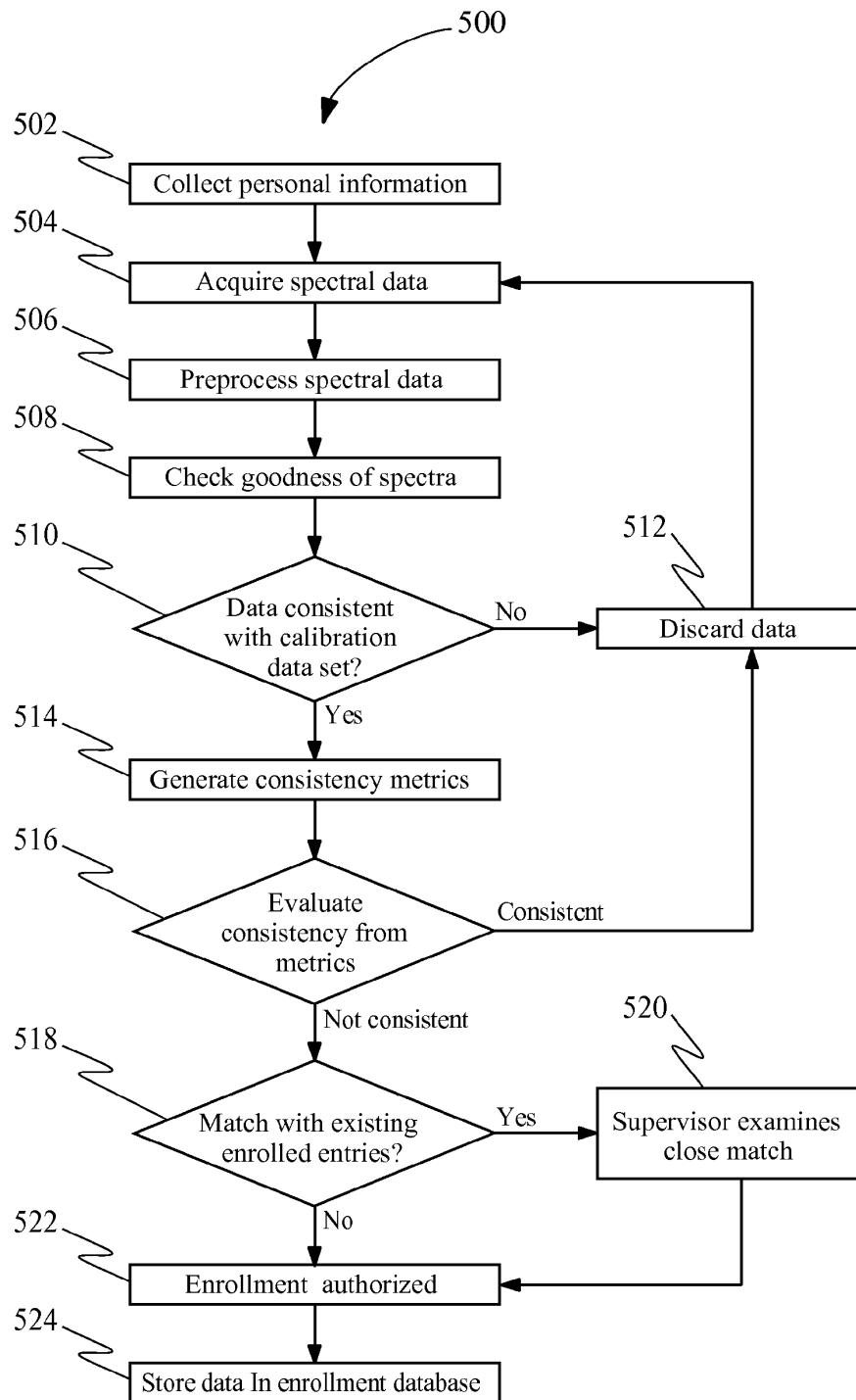


FIG. 10

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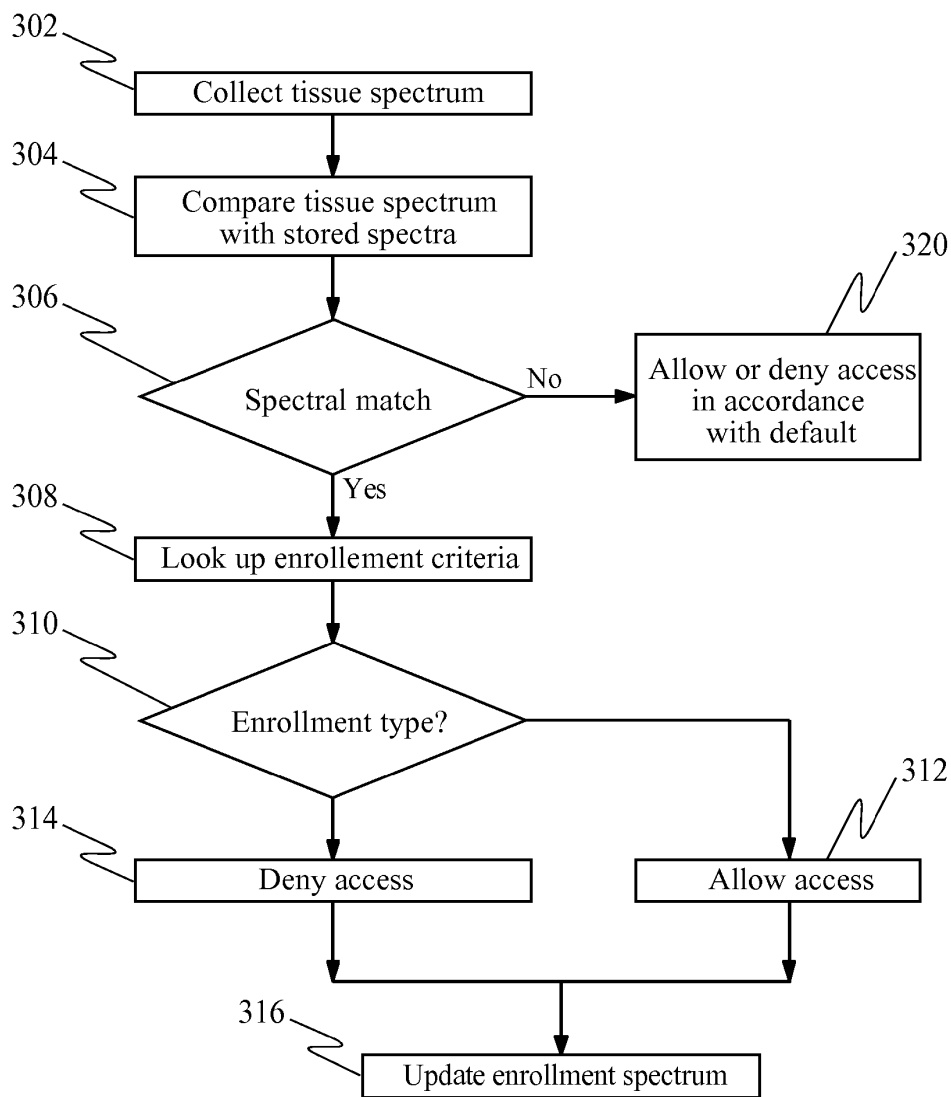


FIG. 11

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ELECTRO-OPTICAL SENSOR**CROSS-REFERENCES TO RELATED APPLICATIONS**

This application is a nonprovisional of and claims the benefit of the filing date of each of the following provisional applications under 35 U.S.C. § 119(e): U.S. Prov. Pat. Appl. No. 60/403,453, entitled "BIOMETRIC ENROLLMENT SYSTEMS AND METHODS," filed Aug. 13, 2002 by Robert K. Rowe et al.; U.S. Prov. Pat. Appl. No. 60/403,452, entitled "BIOMETRIC CALIBRATION AND DATA ACQUISITION SYSTEMS AND METHODS," filed Aug. 13, 2002 by Robert K. Rowe et al.; U.S. Prov. Pat. Appl. No. 60/403,593, entitled "BIOMETRIC SENSORS ON PORTABLE ELECTRONIC DEVICES," filed Aug. 13, 2002 by Robert K. Rowe et al.; U.S. Prov. Pat. Appl. No. 60/403,461, entitled "ULTRA-HIGH-SECURITY IDENTIFICATION SYSTEMS AND METHODS," filed Aug. 13, 2002 by Robert K. Rowe et al.; U.S. Prov. Pat. Appl. No. 60/403,449, entitled "MULTIFUNCTION BIOMETRIC DEVICES," filed Aug. 13, 2002 by Robert K. Rowe et al.; and U.S. Prov. Pat. Appl. No. 60/460,247, entitled "NONINVASIVE ALCOHOL MONITOR," filed Apr. 4, 2003 by Robert K. Rowe et al. The entire disclosure of each of these six provisional applications is incorporated herein by reference for all purposes.

This application is also related to the following commonly assigned applications and patents, the entire disclosure of each of which is incorporated herein by reference for all purposes: U.S. Pat. No. 6,560,352, entitled "APPARATUS AND METHOD OF BIOMETRIC IDENTIFICATION OR VERIFICATION OF INDIVIDUALS USING OPTICAL SPECTROSCOPY," filed Apr. 11, 2001 by Robert K. Rowe et al.; U.S. patent application Ser. No. 09/415,594, entitled "APPARATUS AND METHOD FOR IDENTIFICATION OF INDIVIDUALS BY NEAR-INFRARED SPECTRUM," filed Oct. 8, 1999; U.S. patent application Ser. No. 09/874,740, entitled "APPARATUS AND METHOD OF BIOMETRIC DETERMINATION USING SPECIALIZED OPTICAL SPECTROSCOPY SYSTEM," filed Jun. 5, 2001; U.S. patent application Ser. No. 10/262,403, entitled "SPECTROSCOPIC CROSS-CHANNEL METHOD AND APPARATUS FOR IMPROVED OPTICAL MEASUREMENTS OF TISSUE," filed Sep. 30, 2002 by Robert K. Rowe et al.; and U.S. patent application Ser. No. 10/407,589, entitled "METHODS AND SYSTEMS FOR BIOMETRIC IDENTIFICATION OF INDIVIDUALS USING LINEAR OPTICAL SPECTROSCOPY," filed Apr. 3, 2003 by Robert K. Rowe et al.

BACKGROUND OF THE INVENTION

This application relates generally to electro-optical sensors. More specifically, this application relates to electro-optical sensors for use in biometric analysis of optical spectra of tissue.

Biometric determination is generally defined as the process of measuring and using one or more physical or behavioral features or attributes to gain information about identity, age, or sex of a person, animal, or other biological entity. As well, in order to ensure security, the biometric determination task may include further tasks that ensure that the sample being measured is authentic and being measured on a living being. This latter test is referred to as a determination of liveness.

There are two common modes in which biometric determinations of identity occur: one-to-many (identification) and one-to-one (verification). One-to-many identification

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attempts to answer the question of, "do I know you?" The biometric measurement device collects a set of biometric data and from this information alone it assesses whether the person is a previously seen ("authorized") individual. Systems that perform the one-to-many identification task, such as the FBI's Automatic Fingerprint Identification System (AFIS), are generally very expensive (\$10 million or more) and require many minutes to detect a match between an unknown sample and a large database containing hundreds of thousands or millions of entries. The one-to-one mode of biometric analysis answers the question of, "are you who you say you are?" This mode is used in cases where an individual makes a claim of identity using a user name, a personal identification number (PIN) or other code, a magnetic card, or other means, and the device collects a set of biometric data which it uses to confirm the identity of the person. "Identification" will be used in this document to denote both identification and verification tasks.

Although in general the one-to-many identification task is more difficult than one-to-one, the two tasks become the same as the number of recognized or authorized users for a given biometric device decreases to just a single individual. Situations in which a biometric identification task has only a small number of entries in the authorization database are quite common. For example, biometric access to a residence, to a personal automobile, to a personal computer, to a cellular telephone, and to other such personal devices typically require an authorization database of just a few people.

Biometric identification and verification is useful in many applications. Examples include verifying identity prior to activating machinery or gaining entry to a secure area. Another example would be identification of an individual for matching that individual to records on file for that individual, such as for matching hospital patient records especially when the individual's identity is unknown. Biometric identification is also useful to match police records at the time a suspect is apprehended, but true identity of the suspect is not known. Additional uses of biometric identification or verification include automotive keyless start and entry applications, secure computer and network access applications, automated financial transaction applications, authorized handgun use applications, and time-and-attendance applications. In general, protected property will be the term used to describe all of the goods, places, services, and information that may require biometric authorization to access.

In addition to performing a biometric identification or verification and ensuring that the sample being measured is living tissue, there may also exist a need to determine an estimate of the age, sex, and other demographic characteristics of the person under test as part of the biometric determination task. For example, the U.S. Federal Trade Commission recently established a commission to examine the issue of remotely determining age of a person who is attempting to access a web site in order to block access by children to inappropriate sites. The Commission on Online Child Protection (COPA) heard testimony on Jun. 9, 2000 that indicated that then-known biometric techniques could not be used to aid the determination of a person's age based on any known biometric features.

BRIEF SUMMARY OF THE INVENTION

Embodiments of the invention thus provide methods and systems that extend the functionality of electro-optical sensors. In a first set of embodiments, a device is provided having such extended functionality. The device includes a plurality of light sources, a light detector, and a processor configured to operate the light sources and the light detector to perform a

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plurality of distinct functions. At least one of the distinct functions comprises a biometric identification function in which light is propagated from the plurality of light sources through presented material. The propagated light is received with the light detector, with the presented material being identified from the received light. Another of the distinct functions comprises a nonidentification function performed with the light sources and the light detector.

In some of these embodiments, the light detector may comprise a plurality of light detectors, which may further comprise an array of light detectors. In one embodiment, the nonidentification function comprises a liveness function to determine whether the presented material is alive. Such a determination may be used in some instances as part of providing operation of an optical switch having multistate functionality. In another embodiment, the nonidentification function comprises a nonbiometric function. For example, the nonidentification function may comprise operation of an optical communications port with the light sources and the light detector.

In a second set of embodiments, a portable electronic device having extended functionality is provided. The portable electronic device comprises an electronic arrangement for performing a standard function of the portable electronic device, a biometric sensor, and a processor. The biometric sensor includes a plurality of light sources and a light detector disposed relative to the light sources to detect light from the light sources that has propagated through tissue. The processor is configured to operate the electronic arrangement to perform the standard function and to operate the biometric sensor. Light is propagated from the plurality of light sources through the tissue and the propagated light is received with the light detector. The tissue is identified from the received light.

Examples of functions that may be performed by the electronic arrangement include functions of a cellular telephone, a personal digital assistant, an electronic fob, and a watch. In some instances, the processor may be further configured to operate the biometric sensor to perform a nonbiometric function. For example, the biometric sensor may be operated to perform a spectrometer function, such as a stress-detection function, a lie-detector function, a tanning-meter function, a complexion-monitor function, a toxicity-monitor function, an alcohol-monitor function, a bilirubin-monitor function, a hemoglobin-monitor function, a fruit-ripeness-monitor function, a counterfeit-document detection function, or a color-match function. In other instances, the nonbiometric function may use an illumination capacity of the plurality of light sources and use a detection capacity of the light detector, such as in performing an ambient-light-sensor function, an entertainment function, a personal-security function, a smoke-detector function, a motion-detection function, or an optical-strobe function. In some embodiments, the nonbiometric function may use an illumination capacity of the plurality of light sources, such as to provide an optical-ringer function, a flashlight function, or an optical-pointer function. In other embodiments, the nonbiometric function may use a detection capacity of the light detector, such as to provide a trickle-charge function or a light-meter function.

In a third set of embodiments, a method is provided for managing enrollment in a biometric identification system that accommodates extended functionality. A database is maintained that comprises spectrally derived biometric identification information for at least one individual and an identification of personalized settings for the at least one individual. Collected spectral data are correlated with the spectrally derived biometric identification information for the at least

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one individual. Parameters of an object are adjusted in accordance with the personalized settings. The at least one individual may comprise a plurality of individuals. In some instances, changes to the parameters made by the at least one individual may be tracked so that the personalized settings may be modified in accordance with the changes.

In a fourth set of embodiments, a method is provided for identifying a physiological state of an individual. Electromagnetic radiation is propagated into tissue of the individual. A measured spectral variation is received in the form of electromagnetic radiation scattered from the tissue of the individual. The measured spectral variation is compared with a reference spectral variation over a predetermined wavelength interval by comparing, at each of a plurality of wavelengths within the predetermined wavelength interval, a property of the measured and reference spectral variations. The physiological state of the individual is determined from a consistency of the measured spectral variation with the reference spectral variation.

In some embodiments, the physiological state may indicate a stress level of the individual, while in other embodiments, the physiological state may indicate a level of truthfulness of a statement made by the individual. The measured and reference spectral variations may be acquired substantially contemporaneously, such as in a common session. In other instances, the physiological state may indicate a concentration of a substance in the tissue of the individual, such as a concentration of alcohol, bilirubin, or hemoglobin, among others.

BRIEF DESCRIPTION OF THE DRAWINGS

A further understanding of the nature and advantages of the present invention may be realized by reference to the remaining portions of the specification and the drawings wherein like reference numerals are used throughout the several drawings to refer to similar components. In some instances, a sublabel is associated with a reference numeral and follows a hyphen to denote one of multiple similar components. When reference is made to a reference numeral without specification to an existing sublabel, it is intended to refer to all such multiple similar components.

FIG. 1 provides a perspective view of a spectral biometric sensor used in embodiments of the invention;

FIG. 2 provides a schematic cross-sectional view of a biometric sensor element coupled to a tissue surface showing multiple mean optical paths;

FIG. 3 provides a schematic representation of a top view of a first embodiment of a biometric sensor incorporating multiple light sources arranged with variable source-detector distances;

FIG. 4 provides a schematic representation of a top view of a second embodiment of a biometric sensor incorporating multiple light sources arranged with a common source-detector distance;

FIG. 5 provides a schematic representation of a top view of a third embodiment of a biometric sensor incorporating multiple sources and a waveguide/aperture plate to provide variable source-detector distances;

FIG. 6 provides a schematic representation of a top view of a fourth embodiment of a biometric sensor including multiple light sources and multiple detectors providing variable source-detector separations;

FIG. 7A provides a schematic representation of a top view of a fifth embodiment of a biometric sensor incorporating multiple light sources and multiple detectors providing variable source-detector separations;

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FIG. 7B provides a schematic representation of a top view of a sixth embodiment of a biometric sensor incorporating multiple light sources and a detector array for providing variable source-detector separations;

FIG. 8A provides a schematic representation of a personal biometric sensor built into a key fob;

FIG. 8B provides a schematic representation of a personal biometric sensor built into a backplate of a wristwatch;

FIG. 8C provides a schematic representation of a personal biometric sensor built into a cellular telephone;

FIG. 8D provides a schematic representation of a personal biometric sensor built into a personal digital assistant;

FIG. 8E provides a schematic representation of a personal biometric sensor built into a combined cellular telephone/personal digital assistant;

FIG. 9 provides a schematic representation of a computer system that may be used to manage functionality of biometric sensors in accordance with embodiments of the invention;

FIG. 10 provides a flow diagram illustrating initial biometric enrollment processes in accordance with an embodiment; and

FIG. 11 provides a flow diagram illustrating biometric enrollment management processes in accordance with embodiments of the invention.

DETAILED DESCRIPTION OF THE INVENTION

1. Introduction

Embodiments of the invention are based on the recognition that an accurate, precise, and repeatable tissue spectrum of an individual in certain electromagnetic wavelength ranges contain spectral features and combinations of spectral features that are unique to the individual. In some embodiments, the wavelength ranges comprise the ultraviolet, visible, very-near-infrared, or near-infrared ranges, or combinations of these ranges. In addition, embodiments of the invention recognize that analysis, such as with discriminant-analysis techniques, can identify these unique features or combinations, which may not be readily apparent in visual analysis of a spectral output, so that an individual's identity may be determined by comparison of tissue spectral data taken at the time of use and compared to stored tissue spectral data from prior measurement.

In addition, the tissue spectrum has been found not only to contain information that is unique to an individual, but also to contain numerous features and combinations of features that indicate whether such spectral samples were taken while the sample was alive or not. The physiological effects that give rise to spectral features that indicate the "liveness" state of a sample, i.e. whether it is alive or dead, include, but are not limited to blood perfusion, temperature, hydration status, glucose and other analyte levels, and overall state of tissue decay. Thus, the biometric identification and verification methods of the present invention may also be used in conjunction with, or separately from, the determination of the state of the liveness of the tissue. Tissue from other biological systems, such as organs, animals, etc., has also been found to have spectral characteristics that are distinctly different from human skin due to differences in the tissue composition and form. Thus, the biometric identification methods of the present invention may also be used in conjunction with or separately from the determination of whether the sample is human skin or some other tissue. In addition, it has been found that tissue-like substances such as collagen gelatin, latex, water solutions, or others that have been used to attempt to spoof various biometric sensors have spectral characteristics that are distinctly

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different than human tissue due to differences in composition and form. The biometric identification and verification methods of the present invention can thus be used with or separately from the determination whether the sample is actual tissue or some other substance.

The inventors have also found that other spectral features observed in the tissue spectrum relate to the age and sex of the person being measured. It is believed that these features are due in part to the differences in dermal thickness between young and old people and between males and females. Such changes in skin thickness and composition affect the optical characteristics of the tissue by affecting the scattering properties of the sample. These properties in turn impose distinct spectral shapes on the measured tissue spectra, which can be extracted and used by appropriate multivariate techniques to provide age and sex estimates.

2. Optical Devices

Referring now to FIG. 1, a perspective view of an embodiment of a typical optical sensor head in one embodiment is shown. The sensor assembly 30 comprises a plurality of light sources 34 arranged in a selected manner on a sensor head 32, which also contains one or more detectors 36. The sensor assembly 30 may also include power conditioning electronics (not shown) that supply power to the light sources 34 and may also include signal processing electronics (not shown) that amplify the resulting signal from the detector 36. A multiconductor cable 38 provides a means to power the sensor head and to transmit the detected signal back to a microprocessor or computer (not shown) that processes the spectral data. Alternatively, the power and/or signals to and from the sensor head can be achieved by a direct connection to the supporting electronics or through a variety of electrical interconnects such as PC boards, backplanes, wirebonds, IC connectors, as well as a variety of wireless connections including RF and optical.

The light sources 34 may comprise light emitting diodes ("LEDs"), laser diodes, vertical cavity surface emitting lasers ("VCSELs"), quartz tungsten halogen incandescent bulbs with optical pass-band filters which may optionally include optical shutters, or any of a variety of other optical sources known in the art. The light sources 34 can each have the same wavelength characteristics or can be comprised of sources with different center wavelengths in a spectral range from about 300 nm to about 10,000 nm. In general, the collection of light sources 34 can include some sources that have the same wavelengths as others and some sources that are different. In one embodiment, the light sources 34 includes sets of LEDs, laser diodes, VCSELs, or other solid-state optoelectronic devices with differing wavelength characteristics that lie within the spectral range from about 350 nm to about 1100 nm.

The detector 36 may comprise a single element, a plurality of discrete elements, or a one- or two-dimensional array of elements. The detector type and material is chosen to be appropriate to the source wavelengths and the measurement signal and timing requirements. These detectors can include PbS, PbSe, InSb, InGaAs, MCT, bolometers and micro-bolometer arrays. In one embodiment where the light sources 34 are solid-state optoelectronic devices operating in the spectral range from about 350 nm to about 1100 nm, a suitable detector material is silicon.

The light sources 34 can be sequentially illuminated and extinguished to measure the tissue properties for each source by turning power to each of them on and off. Alternatively, multiple light sources 34 can be electronically modulated

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using encoding methods that are known to one knowledgeable in the art. These encoding patterns include Fourier intensity modulation, Hadamard modulation, random modulation, and other modulation methods.

FIG. 2 shows a cross-sectional view of the sensor head 32 of FIG. 1, for use in diffuse reflectance measurements. Also shown is tissue 40 in contact with the face 39 of the sensor head 32 and the mean optical paths 42, 44, 46, 48, 50, 52 of the light traveling from each light source 41, 43, 45, 47, 49, 51, respectively, to the detector 36. In acquiring tissue spectral data, measurements can be made in at least two different sampling modes. The optical geometry illustrated in FIG. 2 is known as diffuse reflectance sampling geometry where the light sources and detector lie on the same side of the tissue. An alternative method is known as transmission sampling, wherein light enters a thin tissue region such as an earlobe or a fingertip on one side and then is detected by a detector located on the other side of the tissue. Although light in such regions as the silicon-region can penetrate tissue to significant depths of one centimeter or more, depending upon the wavelength, transmission sampling of the tissue limits the region of the body that can be used. Thus, while either mode of sampling is within the scope of the present invention, and especially to analysis utilizing light in the silicon-region, a more versatile sampling method is based upon reflected light.

Referring to FIG. 2, when the tissue is illuminated by a particular light source 41, the resulting signal detected by detector 36 contains information about the tissue optical properties along a path between the source 41 and detector 36. The actual path of any given photon is highly erratic due to effects of optical scattering by the tissue, but the mean optical path 42 is a more regular and smooth curve, as shown in the figure.

This mean optical path is, in general, different for different source-detector separation distances. If another light source 51 is located at the same distance from the detector 36 as light source 41 and the two light sources have the same wavelength characteristics, the resulting signals can be processed as separate elements or can be combined to increase the resulting signal-to-noise ratio of the measurement. If light source 51 has a different wavelength characteristic than light source 41 then, in general, the resulting signals provide unique and useful information about the tissue optical properties, especially as they relate to spectral biometric determinations and may be analyzed as distinct data points. In a similar manner, if two light sources have the same wavelength characteristics and are positioned at different distances from the detector 36 (for example light sources 41 and 43) then the resulting information in the two signals is different and the measurements may be recorded and analyzed as distinct data points. Differences in both wavelength characteristics and source-detector separation provide useful information about the optical characteristics of the tissue 40.

In general, the detector 36 can be located in the center of the sensor head or it can be offset to one side of the sensor head 32 in order to provide for greater source-detector separation distances. The sensor head 32 may have other shapes, including oval, square and rectangular shapes. The sensor head 32 may also have a compound curvature on the optical surface to match the profile of a device in which it is mounted, to incorporate ergonomic features that allow for good optical and mechanical coupling with the tissue being measured, or for other technical or stylistic reasons.

Light that reflects from the topmost layer of skin does not contain significant information about the deeper tissue properties. In fact, reflections from the top surface of tissue (known as "specular" or "shunted" light) are detrimental to

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most optical measurements. For this reason, FIG. 2 illustrates a sensor-head geometry wherein the detector 36 is recessed from the sensor surface 39 in optically opaque material 37 that makes up the body of the sensor head 32. The recessed placement of detector 36 minimizes the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue. It can be seen that the same optical blocking effect could be produced by recessing each of the light sources, or by recessing both the detector and the light sources. Other equivalent means of optical blocking can be readily established by one of ordinary skill in the art. Additionally, a force sensing functionality is sometimes built into the sensor to ensure firm contact between the sensor and the skin, minimizing the amount of shunted light. Such force sensing may be performed in various embodiments with electromechanical switches, capacitive sensors, piezoelectric sensors, or other mechanisms known to one of ordinary skill in the art.

One embodiment of the sensor incorporates an optical relay (not shown) between the sensor surface 39 and the skin 40. This optical relay transfers the light from the light sources to the skin and from the skin back to the detector(s) while minimizing light loss and spreading. Methods of performing this function include fiber-optic face plates and tapers, individual optical fibers and fiber bundles, light pipes and capillaries, and other mechanisms known to one of skill in the art. Optionally, the surface of the light relay can be contoured to fit specific product applications and ergonomic requirements. This has the advantage that the structure of the basic sensor can remain constant, but adapted to various product applications by mounting the sensor to one of a series of optical relay units.

FIG. 3 shows a top view of the sensor head 32 with a plurality of light sources 34 and a single detector 36 visible. This figure is intended to be representative of configurations that allow for a variety of sources 34 and detectors 36 that have variable spacing between them. In general, this configuration is most applicable in cases where a small number of light sources 34 with different wavelength characteristics are available. In these cases, the variable distance between sources 34 and detector 36 are used to gather additional optical information from the tissue.

FIG. 4 shows that the light sources 34 can also be arranged to be equidistant from the detector 36. This configuration is most appropriate in cases where each light source 34 is a different wavelength and sufficient light sources can be obtained to achieve the desired accuracy results for the system. An example of this occurs when the individual light sources are the result of combining optical filters with one or more broadband (e.g., incandescent) light sources. In this case, many unique wavelength bands can be defined and each of the sources 34 can be placed equidistantly from the central detector 36.

An alternative embodiment of a variable source-detector configuration is illustrated in FIG. 5, which schematically depicts a top view of a sensor 70 of this type. In this embodiment, multiple different light sources 71, 74, 77, 80 are arranged around a common detector 83. Four different light sources 71, 74, 77, 80 are shown for illustration but fewer or more can be used in different embodiments. Each of the light sources 71, 74, 77, 80 is optically coupled to a different optical waveguide 72, 75, 78, 81. Each waveguide 72, 75, 78, 81 has individually controllable electronic or mechanical optical shutters 73, 76, 79, 82. These optical shutters 73, 76, 79, 81 can be individually controlled to encode the light by allowing light to enter the tissue from a waveguide 72, 75, 78, 81 at a predetermined position or positions. One method for

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implementing optical shutters is using micro-electromechanical systems (MEMS) structures, which is a technology well known to one of ordinary skill in the art. In specific embodiments, the light sources **71, 74, 77, 80** may comprise different LEDs, laser diodes or VCSELs. Alternatively, one or more incandescent sources with different optical filters can be used to generate light of different wavelength characteristics to couple into each of the waveguides **72, 75, 78, 81**. As well, this MEMS aperture geometry could be used with other illumination sources and geometries illustrated in the other figures in this application.

Alternatively, multiple source-detector distances can also be achieved by using a plurality of detector elements, as shown in FIG. 6. This figure schematically depicts a top view of a sensor **80** of this type. In this embodiment, each of three different light sources **82, 84, 86** is positioned relative to three detectors **81, 83, 85** such that the spacing between a given light source and each of the detectors is different. For example, the source detector spacing for a light source **82** is shortest with respect to detector **85** and longest with respect to detector **83**. By turning on the light sources **82, 84, 86** in a sequential or encoded pattern and measuring the response at each of the three detectors **81, 83, 85**, the tissue characteristics for all of the available source-detector separations at all of the wavelengths can be measured.

Another example of the use of multiple source and detector elements that provide multiple source-detector distances is shown with the top view of FIG. 7A. In this embodiment, the sensor **91** includes a row of detectors **95** surrounded on either side by rows of light sources **93**. In the illustration, five detectors **95** are provided and two rows with eight sources **93** are provided on either side of the detector row, although other numbers and arrangements of the sources **93** and detectors **95** may alternatively be used. The use of multiple detector elements and multiple illumination sources can be extended to using a detector array, as shown in FIG. 7. This figure schematically depicts a top view of a sensor **90** of this type. In this embodiment, multiple light sources **92, 94, 96, 98** are placed at the perimeter of a detector array **99**. The signal detected at each of the array elements then represents a different source-detector separation with respect to the light from a given light source. Many variants on this configuration exist including the use of one-dimensional (1D) or two-dimensional (2D) arrays, and placing sources within the array as well as on the periphery.

The detector(s) can be any material appropriate to the spectral region being detected. For light in the region from about 350 nm to about 1100 nm, a suitable detector material is silicon and can be implemented as a single-element device, a collection of discrete elements, or a 1D or 2D array, depending upon the system configuration and encoding method used. For light in the region from about 1.25 to about 2.5 μm , a suitable detector material is InGaAs and can also be implemented as a single element, a collection of elements, or a 1D or 2D array. Additional detector materials and means of detection include InSb, Ge, MCT, PbS, PbSe, bolometers, and others known to one of ordinary skill in the art.

Once the light passing through the tissue is detected, the signals can be digitized and recorded by standard techniques. The recorded data can then be processed directly or converted into absorbance spectra or noised-scaled absorbance spectra as is known to one of ordinary skill in the art. The data can then be used for spectral identification or verification by the methods described in U.S. Pat. No. 6,560,352, U.S. patent application Ser. No. 09/415,594, and/or U.S. patent application Ser. No. 10/407,589, all of which have been incorporated herein by reference.

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Because of the nature of optical spectroscopy, it is difficult to generate spectra of similar shape and absorbance characteristics without using similar material for the sample. For this reason, many common materials, such as latex and wax that are used to defeat other biometric systems such as fingerprint readers or hand geometry systems are ineffective tissue surrogates for a spectral biometric system. By performing a spectral comparison, most non-tissue samples will be rejected, resulting in a strong countermeasure capability against potential intruders.

Similarly, many of the spectral features that are present in the wavelength ranges disclosed by this invention are indicative of living tissue. These features include oxy- and deoxy-hemoglobin bands, temperature effects, intracellular hydration, and others. These effects contribute to the overall spectral signature of the sample being measured and ensure that a matching sample is one that is part of a living person and normally perfused. Thus, a good spectral comparison ensures the "liveness" of a sample and deters the use of dead or excised tissue as a means to circumvent the spectral biometric system.

In some applications, such as Internet access authorization, it may be useful to be able to verify the sex and/or age of the person using the spectral biometric system. Because of both age- and sex-specific difference in skin structure and composition, the optical spectra change in systematic and indicative ways such that the age and sex can be estimated using the biometric spectral data.

In practicing embodiments of the present invention, the tissue spectral data is determined by measuring the light intensity received by the output sensor for the various light sources which give indications of the optical properties of the tissue at different wavelengths and/or at different source-detector separations. As is well known to one of ordinary skill in the art, the signal produced by the detector in response to the incident light levels can be converted into spectral data that can be recorded and used for subsequent analysis for enrollment or authorization of identity.

3. Exemplary Implementations

A small spectral biometric subassembly, such as those discussed above, can be embedded in a variety of systems and applications. The spectral biometric reader can be configured as a dedicated system that is connected to a PC or a network interface, an ATM, securing an entryway, or allowing access to a particular piece of electronics such as a cellular phone, personal digital assistant ("PDA"), electronic fob, or any other portable electronic device. In this mode, one or more people can be enrolled in the biometric system and use a particular reader to gain access to a particular function or area.

Alternatively, the spectral biometric system can be configured as a personal biometric system that confirms the identity of a person authorized to use the device (who could be one of a plurality of people authorized by the device), and transmits this authorization and any necessary identifying information about the user to any properly equipped PC, ATM, entryway, or piece of electronics, that requires access authorization. The personal biometric could, after confirming the identity of the user, transmit specific user information and device-specific information along with or instead of an authorization. User-specific information may include identity, financial information, medical information, or other pieces of personal information. Device-specific information may include serial number, tamper warnings, battery-low or other service messages, and other pieces of information.

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Instead of performing the biometric authorization procedure onboard the personal biometric system, one can measure the spectral biometric data of the person and transmit the data and any associated identifying information about the user and device to the reader for authentication. One advantage of this latter approach is that the personal biometric system can transmit an identifying code to the reader unit and then use the biometric signal to confirm authorization, which implies that the system needs to perform a verification task rather than the more difficult identification task. Yet, from the user's perspective, the system recognizes the user without an explicit need to identify himself or herself. Thus, the system appears to operate in an identification mode, which is more convenient for the user.

An additional advantage of a personal biometric system is that if an unauthorized person is able to defeat the personal biometric system code for a particular biometric system-person combination, the personal biometric system can be reset or replaced to use a new identifying code and thus re-establish a secure biometric for the authorized person. This capability is in contrast to multi-person biometric systems that base their authorization solely on a biometric signature (spectral, as well as any of the other biometric techniques such as fingerprint, iris, facial, etc.). In this latter case, if an intruder is able to compromise the system by somehow imitating the signal from an authorized user, there is no capability to change the biometric code since it is based solely on a fixed physiological characteristic of a person.

FIG. 8A shows one embodiment of a personal spectral biometric system 100 in the configuration of an electronic key fob 102. The equidistant sensor configuration of FIG. 4 is shown for illustration purposes only; more generally, any of the disclosed sensor configurations (or other equivalent configurations) may be implemented in the electronic key fob. The illumination 104 and detection system 106 are built into the fob 102, as are the data collection and digitization devices for collecting and digitizing the spectral information. In one embodiment, short-range wireless techniques based upon RF signals 103 can be transmitted to communicate between the fob and a corresponding reader (not shown) that allows access to the PC, entryway, etc. In another embodiment, an infrared optical signal can be used to transmit the information between the fob and the reader. In another embodiment, a direct electrical connection is established between the personal biometric system and the reader. The actual comparison between the measured spectral data and the previously recorded enrollment spectrum (template) can be made either within the fob or at the reader. In the former case, the logical operations necessary to perform the comparison are done within the fob and then a simple confirmed or denied signal is transmitted to the reader. In the latter case, the most recent measured spectrum is transmitted to the reader and the comparison and decision is accomplished at the reader or at a host to which the reader is connected. In either case, the communication between the fob and the reader needs to be performed in a secure manner to avoid interception and unauthorized use of the system. Methods for ensuring secure communication between two devices are well known to one of ordinary skill in the art.

A second embodiment of a personal spectral biometric system 110 is depicted in FIG. 8B. In this case, the biometric reader 111 is built into the case of a wristwatch 112 and operates based upon signals detected from the skin in the area of the wrist. The operation of this system is identical to the operation described for the biometric fob. FIG. 8B again shows the equidistant-sensor geometry of FIG. 4 for illustration purposes only; more generally, any of the sensor geom-

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etries previously disclosed or other equivalent configurations can be used for this application.

In addition to the watch or fob, similar biometric capability can be built into other personal electronic devices. For example, FIG. 8C provides side and back schematic illustrations of a cellular telephone 120 that comprises a biometric reader 122. In this instance, the biometric reader 122 is shown on the back of the cellular telephone 120, although it may be placed in other positions as well. FIG. 8C shows the variable-spacing sensor geometry of the biometric reader 122 described with respect to FIG. 3 for illustration purposes only; more generally, any of the sensor geometries previously disclosed or other equivalent configurations can be used for this application. The operation of the biometric reader 122 in the cellular telephone 120 may be similar to that described in connection with FIG. 8A for the fob, with data collection and digitization devices being included internal to the cellular telephone. Comparisons between measured spectral data and a previously recorded enrollment spectrum may be made within the cellular telephone 120 or at a separated reader.

FIG. 8D provides a further example of a personal electronic device that may be configured with biometric capability in the form of a PDA 130, with both side and front schematic views. In this instance, the biometric capability is provided with a biometric reader 132 on the side of the PDA 130, although other alternative positions may be used. The variable-spacing sensor geometry described with respect to FIG. 3 is used to illustrate one form of the biometric reader 132, in this case having light sources distributed elliptically about the detector; more generally, any of the sensor geometries previously disclosed or other equivalent configurations can be used for this application. As for the other devices, data collection and digitization devices may be included internally to the PDA 130 to perform data collection and digitization functions. Comparisons between measure spectral data and an enrollment spectrum may be made within the PDA 130 or at a separated reader.

Still another example of a personal electronic device configured with biometric capability in accordance with an embodiment of the invention is shown in FIG. 8E for a combined cellular telephone/PDA 140 with top and front views. The location of the biometric reader 142 may be in any suitable location, but is shown on the top for illustrative purposes. The illustration of the biometric reader 142 having the variable-spacing geometry described with respect to FIG. 3 is again not intended to be limiting since any of the previously disclosed sensor geometries or other equivalent configurations may alternatively be used.

Still other devices may be configured to include the biometric sensor in other embodiments. For example, the compact sensors disclosed can also be put into firearms to prevent unauthorized usage. In particular, the biometric sensor could be placed in the handgrip of a weapon such as a handgun or other firearm to sense tissue properties while the gun is being held in a normal manner.

Management of the functionality discussed herein for the biometric sensor may be performed with a computer system. The arrangement shown in FIG. 9 includes a number of components that may be appropriate for a larger system; smaller systems that are integrated with portable devices may use fewer of the components. FIG. 9 broadly illustrates how individual system elements may be implemented in a separated or more integrated manner. The computational device 330 is shown comprised of hardware elements that are electrically coupled via bus 342, which is also coupled with the biometric sensor 356. The hardware elements include a processor 332, an input device 334, an output device 334, a storage device

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338, a computer-readable storage media reader 340a, a communications system 344, a processing acceleration unit 346 such as a DSP or special-purpose processor, and a memory 348. The computer-readable storage media reader 340a is further connected to a computer-readable storage medium 340b, the combination comprehensively representing remote, local, fixed, and/or removable storage devices plus storage media for temporarily and/or more permanently containing computer-readable information. The communications system 344 may comprise a wired, wireless, modem, and/or other type of interfacing connection and permits data to be exchanged with external devices. The storage devices typically hold information defining the stored spectra as well as any personalized-setting information that may be used.

The computational device 330 also comprises software elements, shown as being currently located within working memory 350, including an operating system 352 and other code 354, such as a program designed to implement methods of the invention. It will be apparent to those skilled in the art that substantial variations may be used in accordance with specific requirements. For example, customized hardware might also be used and/or particular elements might be implemented in hardware, software (including portable software, such as applets), or both. Further, connection to other computing devices such as network input/output devices may be employed.

4. Enrollment Functions

a. Initial Enrollment

In FIG. 10 the major elements of a spectral biometric enrollment sequence 500 are shown. Since a successful enrollment authorizes the user for future access to the systems or services protected by the biometric, the enrollment sequence 500 is generally performed under secure means or controlled situations. Where applicable, enrollment might be supervised by an authorized person (e.g. for a bank clerk would have to supervise enrollment in a biometric system used for automated financial transactions) or take place in an authorized location (e.g. enrollment for a biometrically enabled automobile might have to occur at an authorized car dealership), or take place when an authorizing token is presented (e.g. a password or key is used to start the enrollment process), or take place under authorized conditions (e.g. a biometrically enabled cell phone can only be initialized when located in a particular authorized household), or occur only when a device is first activated or reset.

Once the enrollment is enabled, the sequence 500 begins with the collection of personal information 502, which is linked to the spectral biometric data. At a minimum, this personal information consists of a unique identifier that can be used by automated or manual means to refer to the particular biometric enrollment data. The personal information can also include items such as name, addresses, contact information, demographic information, medical information, passwords and PIN's for other systems, authorization codes, links to other databases or systems, and any other information pertinent to the particular biometric application. These information can be entered by a variety of means including manual entry during an enrollment interview, read automatically from a magnetic card, proximity card, or smart card, or downloaded from other systems and databases.

When the collection of personal information 502 is complete, the next block shown in the sequence is the acquisition of spectral data 504. The acquisition commences when the person being enrolled places the appropriate portion of the hand or other body part in contact with the spectral biometric

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sensor and a trigger is given. The trigger can be manually activated or based on a mechanical, optical, electrical or magnetic switch that senses contact between the sensor and the skin site being enrolled. As few as a single enrollment sample can be taken, but more typically two or more independent samples are taken to ensure that the samples are consistent, as explained later in the sequence. If multiple enrollment samples are taken, the person being enrolled typically withdraws their hand from the sensor and replaces it in order to collect a new independent sample.

Once the candidate enrollment sample or samples are collected, they may undergo one or more preprocessing operations 506. Preprocessing of the spectral data may include a decoding step if the data were collected in an encoded fashion such as Hadamard, Fourier, frequency division multiplexing, spread spectrum techniques, and others of similar nature. Operations necessary to invert the encoding imposed by such techniques are well known to one of ordinary skill in the art. Other systems such as sequential illumination of different wavelength sources do not require decoding.

Whether or not the data are required to be decoded, additional preprocessing steps may include generating the ratio of the biometric spectra to an optical reference spectrum, performing a logarithmic transform of the spectral data, performing explicit corrections to account for sensor-to-sensor variations or environmental influences of temperature, humidity and pressure, scaling the data by some function, and selecting certain subsets of the spectral data for further processing. These and other techniques are well known in the art.

After preprocessing, if any, the spectra can then be checked for goodness 508, which confirms that the candidate enrollment spectra have optical characteristics that are similar to the type of tissue for which the sensor is calibrated. In particular, if the goodness check 508 generates a metric or metrics that ensures that the enrollment samples have optical properties that are similar to living skin collected from a human hand (for example). As such, this procedure performs the spectral liveness determination for the enrollment data. In order to do this, the candidate enrollment samples are compared to calibration factors that describe the spectral qualities of the calibration samples (which in this example are presumed to be taken from the skin on one or more living human hands). These factors can be generated using a variety of standard techniques including principal component analysis, linear discriminant analysis, partial least squares, Fourier analysis, cluster analysis and other numerical modeling methods known to one of ordinary skill in the art.

Analyses and metrics that can be used to ensure that the candidate enrollment samples are good (i.e. consistent with the calibration data) include Mahalanobis distance, Euclidean distance, residuals of the enrollment spectra when fit by the calibration factors, cluster analysis and other methods that are known to one of ordinary skill in the art (see for example, *Multivariate Calibration* by Martens and Naes, John Wiley & Sons, 1993, chapter 5, which is incorporated herein by reference). The goodness decision 510 is based on one or more of these metrics to determine if each of the candidate enrollment spectra is consistent with the calibration data set. If so, the enrollment process continues with a consistency check described below. If not, the candidate enrollment data are discarded at block 512 (either all enrollment samples or only the ones that are deemed to be not good) and new enrollment data are collected to replace them. There are also a variety of logical options that the enrollment process can be incorporated in this loop that are not shown, such as a try counter to permit a limited number of enrollment attempts before flagging an error condition.

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The next step in the enrollment process **500** is the generation of consistency metrics **514** followed by a consistency decision **516** based on those metrics. The consistency check confirms that the multiple candidate enrollment samples are sufficiently similar to each other to take them as valid. This portion over the overall procedure **500** is omitted in cases where the system operates with only a single candidate enrollment spectrum is taken. In cases where a consistency determination **516** is performed, the methods used can be similar to the methods used for goodness **510** with the difference being that the enrollment spectra are compared to themselves instead of compared to the calibration data. As an example, consider the case where Mahalanobis distance is used as a metric for both the goodness **508** and consistency **514** steps. In the case of goodness, the spectral mean of the calibration data is subtracted from each of the candidate enrollment data and the Mahalanobis distance of this difference is calculated. If the distance is consistent with the distances that the mean-centered calibration data produced, then the goodness according to this metric is acceptable. Conversely, when using the same data and same metric for a consistency check, the mean of the candidate enrollment spectra themselves are subtracted from each of the candidate spectra (or other similar operations can be performed such as subtracting on of the candidate spectra from each of the others). If the resulting Mahalanobis distances are sufficiently small, then the candidate enrollment spectra are deemed to be consistent in the consistency decision **516**.

The outcome of the consistency decision **516** has similar options and results as the goodness decision **510**. In the case where the candidate enrollment samples are found to be inconsistent, some or all of the samples are retaken. In the case where the samples are found to be consistent, then the enrollment process **500** may proceed to check for a match with the existing enrolled entries **518**. Determining where there is a match with the existing enrolled data is particularly important in a biometric system that is being used in an identification mode where participants may have an incentive to assume false identities. Examples of such situations include biometrics systems used to authorize voting, the issuance of a driver's license, identification card, passport, credit card, welfare benefits or other item of tangible value.

Matching against the enrolled database **518** relies on the use of specific, predetermined spectral features or factors. These factors are determined during an earlier calibration phase and are chosen to enhance person-to-person effects relative to typical spectral changes experienced by a single person or changes that occur within and between biometric sensors. Examples of techniques for generating the factors include principal component analysis, linear discriminant analysis, quadratic discriminant analysis, partial least squares, and other multivariate methods as is known to one of skill in the art. In one embodiment, the factors for determining a match to the enrolled database **518** are generated using principal component analysis (PCA) operating on a set of calibration data that have been collected from multiple people in multiple environmental conditions over time spans that are representative for the actual operation of the biometric sensor.

In the case where a close match is found, a properly authorized supervisor can examine the pertinent details at block **520** and decide whether to authorize the enrollment **522** based on any evidence of falsification. In the cases where either no close matches are found or a supervisor authorizes enrollment in the presence of a close match at block **522**, the enrollment data are stored in the enrollment database **524** and the enrollment process is completed.

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b. Other Enrollment Functions

Several embodiments of the invention provide methods for managing enrollment. An outline of several aspects of such enrollment management is presented in FIG. 11, which provides an overview of an identification or verification function in the form of a flow diagram. When the identity of an individual is to be checked to determine whether to allow or deny access, a tissue spectrum is collected from the individual at block **302** using one of the methods and systems described above. The collected tissue spectrum is compared with a set of one or more stored spectra at block **304**. Such a comparison includes extracting the relevant identification indicia from the spectra as described above and examining corresponding database entries. Identification of a match between the collected spectrum and a stored spectrum at block **306** generally comprises ensuring that the relevant identification indicia differ by less than a predetermined threshold.

If there is no match between the collected spectrum and any of the stored spectra, the individual is either allowed access or denied access in accordance with a default setting of the system. It is expected more usually that the inability of the system to identify the individual will result in a default denial of access. If a spectral match is found at block **306**, it is possible for the system to respond in a similar default manner, such as by providing access to any individuals that are properly identified. The flow diagram indicates additional embodiments, however, that provide for the possibility of specific denial of access to certain identified individuals. At block **308**, enrollment criteria for the identified individual indicating whether that person is to be allowed or denied access are examined. In accordance with the check at block **310**, access is either allowed or denied at block **312** or **314** depending on the enrollment type of the individual.

The ability to identify individuals who are explicitly to be denied access, as opposed to denying access on a default basis to those who cannot be identified, provides a number of advantages to the system. For example, if the biometric sensor is comprised by a handgun, the system may identify the owner as the only individual permitted to use the device, and may additionally explicitly prohibit individuals identified as the owner's children from using the device. Thus, in accordance with the flow diagram of FIG. 11, when the owner wishes to use the device, his identity is confirmed at block **306** and he is allowed access at block **312**. When an unknown party attempts to use the device, he is denied access on a default basis at block **320**. When one of the identified owner's children attempts to use the device, however, access is denied explicitly at block **314**. Such explicit denial provides greater security against misuse of the device.

It is also possible to use the explicit-denial capability of a biometric system in a fixed installation such as a home, place of business, or an automobile. For example, a biometric system installed at the entryway of a place of business can be used to admit authorized employees and temporary workers. If an employee is fired or the term of the temporary employee expires, then their enrollment data can be shifted from the authorized to the unauthorized database, and an explicit check is made to deny access to the former employee if he or she attempts to enter.

In some embodiments, allowing access at block **312** may also comprise personalizing settings. For example, supplementary information regarding the identified individual may be stored in addition to storing identification indicia. This supplementary information may also be updated over time to reflect better identification of settings suitable for each individual. For example, in one embodiment the biometric sensor is comprised by an automobile that is used by multiple indi-

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viduals and acts as a security device. When one of those individuals accesses the automobile, she is not only provided with access to it at block 312, but environmental aspects such as seat positions, radio settings, temperature, etc. and safety characteristics such as air-bag deployment profiles are automatically configured for her. In another embodiment, the biometric sensor is comprised by a television remote control and is positioned to identify the individual holding the device automatically. A processor programmed to track viewing habits is configured to discriminate by the identified individual. Thus, over time, whenever one of the individuals handles the remote control, it may automatically adjust settings, such as selecting certain preferred channels, volume levels, etc., that are individualized. The preceding are examples in which the biometric sensor is used to automatically personalize the device or environment to the specific person's requirements or tastes.

In applications that are dedicated to personalization tasks rather than providing security against unauthorized usage, a further processing step on initial enrollment may be performed. Once a good enrollment spectrum is collected, or an existing enrollment spectrum is updated, a mathematical analysis is initiated to determine features that best separate the existing enrolled users. The result of this discriminant analysis then modifies the calibration coefficients that are used in blocks 304 and 306 of FIG. 11 to determine a matching tissue spectrum. The ability to customize the calibration coefficients for a particular set of enrolled users in this way allows the overall performance of the personalization task to be improved.

Block 316 of FIG. 11 indicates another enrollment aspect included in certain embodiments of the invention. Over time, it is possible for changes to occur in any living system that may result in changes to the spectral identification indicia used in embodiments of the invention. These differences are generally insufficiently large to prevent a proper identification, but may accumulate over time. In a similar manner, small but progressive changes in the sensor due to aging, wear or environmental effects can also accumulate to significant levels. Thus, in either case, once a spectrum collected at block 302 is authenticated, an update may be performed of the stored spectrum at block 316 to reflect the differences between the current spectrum and the stored enrollment. While such an update could comprise substituting the stored spectrum with the collected spectrum, more generally the method uses a weighting averaging technique to mitigate sharp changes.

Such an updating technique may also be used in other embodiments. For example, spectral variations may also result from differences in individual biometric sensor arrangements. Thus, in one embodiment, a spectral profile for each individual is stored for each sensor, either locally to the sensor or centrally with an identification of the sensor. Updates are then performed for each sensor when an individual uses it for identification, having the effect of tuning each biometric sensor to its own individual characteristics.

The enrollment-management methods described with respect to FIG. 11 may be implemented on a computational device such as the one illustrated schematically in FIG. 9.

5. Extended Functionality

A number of embodiments of the invention exploit the illumination and/or light-detection capabilities provided by the biometric sensor. These capabilities are used to provide functions that are supplementary to the identification and/or verification functions. As such, these embodiments are espe-

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cially suitable when the biometric sensor is comprised by a portable device, such as a portable electronic device. In some embodiments, activation of the supplementary functions may be tied with a service contract. In these instances, some of the functions may be of interest to a customer for a modest increase in service fee even if the customer would not be inclined to purchase a separate device dedicated to performing those functions. For example, in one embodiment, the biometric sensor is comprised by a cellular telephone. The cell-phone provider offers extended functionality of the biometric sensor in accordance with the embodiments described below for the modest fee surcharge.

a. Spectrometer Capabilities

In one set of embodiments, the spectral-analysis capabilities of the biometric sensor are extended to spectral analysis of material other than tissue. While a number of specific examples are provided to illustrate such extended functionality, the examples are not intended to be limiting and several other examples will be evident to those of skill in the art after reading this description. In some of the embodiments, the spectral-analysis capabilities are to identify changes, such as for the detection of conditions in humans that manifest themselves through spectroscopic changes in skin or other tissue. In other embodiments, the spectral-analysis is performed according to an absolute scale where the specific spectral characteristics are independently relevant. In some of the specific embodiments discussed below, the spectral analysis is used to identify a physiological state of an individual. Identification of such a physiological state may be made by measuring the spectral variation of a measured spectrum for light scattered by tissue of the individual, and comparing it with a reference spectral variation. The consistency of the measured spectral variation with the reference spectral variation allows a determination of the physiological state.

For example, in one embodiment, the extended functionality comprises a stress and/or lie detector. It is known that stress in humans causes a characteristic change in skin color, usually reddening, that may be detected spectroscopically. The change in skin color is believed to result from changes in the flow of blood in tissue as a result of the stress. This extended functionality may be included in the device by storing a reference spectrum for individuals when they are not under stress. When a subsequent spectrum is measured in accordance with the descriptions above, it may be compared to the reference spectrum using an appropriate multivariate discrimination method such as linear or quadratic discriminant analysis to determine whether such indicia of stress are present. In some cases, the measured and reference spectra may be acquired close in time. For example, during a questioning session, an initial spectral baseline may be determined by having a subject respond to a base set of questions in a known manner, responding truthfully to some and falsely to others. These results then effectively provide a spectral calibration against which the response to questions whose truthfulness is unknown may be measured.

In another embodiment, the extended functionality comprises a tanning meter. Similar to the stress and/or lie detector, functionality as a tanning meter is included by identifying changes in skin color, in this instance in response to exposure to sunlight or other ultraviolet radiation, such as may be provided in a tanning booth. An advantage to this use of the device is that exposure levels may be quantified on an individual basis and close in time to the tanning activity in order to rapidly determine sufficient exposure and avoid overexposure. Other techniques for determining excessive exposure are qualitative, relying on such broad factors as general skin type, eye color, hair color, etc. These qualitative techniques

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provide, at best, a crude estimation of excessive exposure. Use of the spectral analysis provided by embodiments of the invention instead provides much more accurate information.

In a further embodiment, the extended functionality comprises a complexion monitor. In a number of applications, notably in the cosmetics industry, skin color and composition are used as a guide, such as for choices in make-up color, hair-dye color, clothing color, etc. Qualities of the skin of interest in this application may include amount and type of collagen, melanin, elastin, sebum, hemoglobin, moisture content, skin surface characteristics, and other physiological, chemical, and structural characteristics of the skin. The ability of embodiments of the invention to quantify skin characteristics permits more reliable choices than provided by purely qualitative evaluations of skin color.

In some instances, the physiological state of an individual may be defined by concentration of a substance in the individual's tissue. For instance, the extended functionality may comprise a hemoglobin monitor. Similar to the effects of stress, increased activity levels in individuals as well as certain medical conditions are manifested by changes in blood flow in the body. Such changes in blood flow cause spectroscopic changes that may be detected according to the methods described above. According to this embodiment, these spectroscopic changes are correlated with oxygenation and/or hemoglobin levels in the blood. In addition to medical uses, the ability to quantify oxygenation levels is useful for individuals in monitoring exercise levels.

Spectroscopic changes associated with different physiological states in human tissue may also result from the release of certain pigments in response to pathological conditions. One example is provided by bilirubin, which is a reddish bile pigment that is released when liver tissue is diseased. The presence of the pigment causes a jaundicing of the affected person's skin. Such changes in skin color may be identified using the methods described above. Accordingly, in one embodiment, an extended functionality of the biometric sensor allows it to function as a bilirubin monitor. In other embodiments, levels of other pigments may similarly be monitored.

The presence of toxic substances in an individual's blood may also manifest itself spectroscopically because of the effect such toxins have on vascularity as well as a direct spectroscopic signature in certain cases. For example, increases in alcohol levels result in spectroscopic changes that may be observed, particularly in the infrared portion of the electromagnetic spectrum. Thus, a further extended functionality of the biometric sensor permits it to function as an alcohol monitor. In other embodiments, the levels of other toxins and/or drugs may be similarly monitored.

While the above examples have focused on uses that correspond to identifying conditions in humans, it will be appreciated that similar spectroscopic information permits the extended functionality also to be used for veterinary purposes. Moreover, spectroscopic information may also be used in quantifying the quality of plant tissues. For example, in one embodiment, the extended functionality comprises use as a fruit-ripeness monitor. Color changes are a natural part of the ripening process for fruit, and these changes may be detected using the methods described above. Accordingly, a portable electronic device that includes a sensor of the type described above may conveniently be used to test the ripeness of fruit.

Spectroscopic information is also of use in characterizing inorganic materials. Thus, in another embodiment, the device may be used for matching the colors of paints, textiles, and other materials. Such information can be used, for example, to match colors of paint and other coatings, or to determine

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complimentary colors of textiles, clothing, etc. As a further example, ink colors used in documents such as currency and other government documents may be quantified. Comparison of measured spectra for such documents with stored spectral characteristics of approved inks permits the identification of counterfeit documents. Thus, a portable electronic device that includes a sensor of the type described above may be provided with extended functionality as a counterfeit-currency detector.

b. Combined Illumination and Detection Components

In other embodiments, additional extended functionality is provided by using combined illumination and detection capabilities of the biometric sensor. For example, in one embodiment, the device is used as a smart optical switch. In such an embodiment, the ability of the device to identify the liveness of tissue, as described above, is used so that an electronic device is turned on only when touched by living tissue, usually the finger of a person. Such functionality is particularly useful in the context of portable electronic devices, which are often left in purses, briefcases, pockets or other places where they may be activated inadvertently, possibly wasting significant battery life. Such inadvertent activation is avoided by the ability to confirm liveness of an object that touches the switch. As well, the smart switch functionality is applicable to power tools, manufacturing equipment, industrial machinery, and other potentially dangerous environments and conditions. In each of these cases, a smart switch can be used to ensure that the tool, piece of equipment, manufacturing station, etc. was turned on intentionally by a human hand or hands rather than by an accidental touch of an inanimate object. In cases where the smart switch functionality is the sole functionality required of the device, the configuration of the device can be simplified relative to a biometric sensor. More generally, however, the multifunction capabilities, including the smart optical switch, may be included with any implementation of the biometric sensor.

The optical switch may also be configured with trinary functionality in some embodiments. Such functionality may respond to different pressure levels with which a finger presses the optical switch. Such differences in pressure levels affect the optical properties of skin through a variety of physiological phenomena including changes in local tissue perfusion, changes in water volume, and other changes in the optical scattering and absorbance properties of the tissue that are close to the area in contact with the sensor. In general, these changes in the optical properties of the tissue are related to the pressure between the tissue and the sensor, and thereby the pressure can be ascertained optically. Thus, in one embodiment, the trinary functionality corresponds to the three states where (1) the switch is untouched, (2) the switch is touched lightly, and (3) the switch is touched firmly. Still more levels of functionality may be provided, such as where a fourth level corresponds to where the switch is touched with intermediate firmness. In principle, arbitrarily many levels of functionality may be included, although it is generally more difficult for an individual to discriminate levels of firmness if there are more than three or four levels. Since no moving parts are provided for the optical switch, there is no danger that mechanical parts will break or wear. In addition, the absence of mechanical parts makes the switch especially suitable for use with hermetically sealed packages where contamination by air and/or water is to be avoided.

In a further embodiment, the illumination and detection capabilities provided by the biometric sensor are combined to provide an ambient light sensor. In one such embodiment, the level of backlighting on a portable electronic device is adjusted in response to the ambient level of light in order to

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conserve battery life. For example, the backlight may be increased when the light level is low, such as in a dark room or at night, and decreased when the light level is high, such as during daytime.

In a specific embodiment, the device is configured to discriminate between darkness where the portable electronic device may be used, such as in a dark room or at night, and darkness where the portable electronic device is being stored, such as in a purse or briefcase. These different positions are distinguished by using a reflectance burst when darkness is identified. In a relatively small enclosed space, light is reflected back and detected by the light detector; in such cases, the backlighting is kept very low. In a larger space, such as a room or outdoors, the burst light is not reflected back to the device; accordingly, the backlighting is increased. Alternatively, the ambient sensing capability can be combined with a liveness sensing capability to sense the ambient light level only during or after the sensor has been activated by a genuine sample.

In another embodiment, the combined illumination and detection capabilities are used to provide extended functionality as a bar-code scanner. The bar code scanning capabilities are provided by using the light source to illuminate a bar code and by analyzing the spectrum received by the light detector to deduce the bar code. Such functionality may be used in numerous varied applications, some of which are indicated explicitly herein. For example, in one embodiment, the bar code scanning capability is used to provide an information service. For example, when the sensor is comprised by a portable electronic device that is equipped to access the Internet, scanning of a bar code causes the device to retrieve corresponding information from the Internet and to display the retrieved information on the portable electronic device. Alternatively, certain information may be retrieved directly from a storage device resident on the portable electronic device.

These capabilities permit a user to obtain product information quickly. In some instances, the request for information initiated by the scanning function is additionally recorded for marketing purposes. In particular, the scanning request, coupled with the biometric identification functions of the sensor provide information identifying a person and the type of information being requested. In some cases, this may also be coupled with location information, such as where the portable electronic device includes a GPS transponder. As information requests are made by the user, they may be compiled and subsequently analyzed for directed marketing.

In a particular embodiment, such directed marketing may be substantially contemporaneous with the scanning request. For example, a consumer may be shopping in a grocery store and is trying to decide which of several similar products to purchase. By scanning them to obtain additional information, a remote system may be provided with sufficient information to recognize the consumer's interest. Accordingly, an electronic coupon for a particular one of the products may be immediately directed to the consumer's portable electronic device for immediate use.

Another capability of the bar-code-scanning functionality may be illustrated in the form of a grocery-list compiler. For example, when this capability is enabled in a particular portable electronic device, a simple scan of an item in a household can be made whenever that item is depleted. A record is stored of the fact that the item is now needed, and these records accumulate over time. When the individual is ready to shop for groceries, a simple command on the portable electronic device provides the accumulated shopping list to identify those items for purchase. In an alternative embodiment,

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items may be added to the list remotely when two portable electronic devices are equipped to communicate with each other. Such an embodiment is useful where a first person is already at the store shopping and a second individual identifies an additional item for purchase. The item is scanned at home and is immediately added to the list at the store.

A further extended functionality that uses the combined illumination and detection capabilities of the sensor permits it to be used as an optical communications port. In such embodiments, the light sources provide encoded optical signals for transmission over short-distance connections. Similarly, the light detectors receive the encoded optical signals from a similarly equipped device. Typical applications for this extended functionality are the ability to use a cellular telephone or PDA as a television remote control and to communicate reprogramming functions to device. In some instances, the light detectors may be configured to respond to certain wavelengths, enabling the implementation of high-bandwidth, full-duplex optical communication.

The functionality of the sensor may also be extended to provide various entertainment functions. For example, in some embodiments, it may be integrated as part of a game provided on a portable electronic device. One aspect of the sensor, in particular, that may be integrated into games is its multiplicity of distinct colors. There are numerous different games that may use such a color feature, one of which is a memory game that requires the player to repeat a color sequence, similar to the game "SIMON." Another game that integrates the functionality of the sensor is an increasingly popular version of "phone tag," in which participants use GPS systems to locate other participants on cellular telephones. Confirmation that a participant has been found may be confirmed by using the biometric sensor described herein. Another entertainment function may use the sensor as a mood meter, providing a description of an individual's mood based on a spectral analysis of her skin.

The functionality of the sensor may also be extended to provide personal-security functions. For example, if the biometric sensor is configured to operate at infrared wavelengths, it may not require actual physical contact in order to perform identifications, but may instead rely on reflected infrared light or even black-body emissions in the infrared region of the electromagnetic spectrum. A variation of this embodiment that provides personal security functions permits the biometric sensor to detect motion at infrared wavelengths. Such a function is useful, for example, for travelers. The motion detection may be integrated with an alarm function so that an alarm is sounded when motion is detected. If the sensor is comprised by a cellular telephone or other portable electronic device, it may alternatively be configured automatically to dial an emergency number.

Another variation of the remote security functionality is offered by configuring the biometric sensor to be sensitive to mid-infrared wavelengths. In this way emitted black-body radiation can be used as the illumination source and the biometric determination can be done remotely, without physically contacting the sensor. In cases where it is desirable to determine that something moved, it is possible to just monitor changes in the amount of reflected or emitted light over time. In other cases where it is important to ensure that the light passes through the skin before being detected (such as a biometric determination), it is also possible to configure a sensor with active illumination to operate remotely by ensuring that the illumination spot and the spot of skin being detected do not overlap. In this way, detected light is ensured to have traveled through the skin rather than simply reflected from the surface. Optical systems for performing such a

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remote measurement can be developed from lenses, mirrors or other optical elements as known to one of skill in the art.

A further example of a personal-security function that may be provided as part of the extended functionality is a smoke detector. Such a detector may emit light from the light source and be configured to detect light reflected from particles in air as would result from the presence of smoke in a room. Such a feature may also be integrated with an alarm function or with an automatic dial function to respond to presence of smoke.

An additional example of an extended functionality is provided by an optical-strobe function. This function may use the illumination components to produce strobed light and may provide a feedback function based on the detection of reflected light to tune the frequency of the strobe. Such tuning may be applied, for example, to tune strings on musical instruments, such as guitars.

c. Use of Illumination Component

In other embodiments of the invention, extended functionality is provided using only the illumination capabilities provided by the biometric sensor. A simple example that illustrates such extended functionality is a flashlight capability. This capability is achieved simply by activating the light source(s). In some instances, the light source(s) may be configured to be substantially monochromatic and/or to be highly directional, permitting operation as a laser pointer.

More complex extended functionality makes use of the different colors that are available with the light sources. For example, a cellular telephone may use the sensor as an optical ringer, which functions to alert the owner to an incoming call in addition to or instead of by issuing an audible noise. An optical ringer is especially useful in circumstances where an audible ring would be intrusive, such as in a meeting, or would be difficult to detect, such as in a noisy environment. An optical ringer may also be used by people having a hearing impairment, who may nevertheless use short message services ("SMS") that are available for cellular telephones. The color capability is used in certain embodiments to identify the caller by correlating the originating telephone number with a predefined color. Also, in certain embodiments, particular optical-ring patterns may be downloadable.

According to embodiments of the invention, specific sequences of colors may also be presented with the sensor as a form of branding to identify a product or service source. For example, in response to identifying an individual, a distinct temporal sequence of colors may be presented with the light sources. If the sensor is comprised by a product, such as a portable electronic device, the temporal sequence may be associated with the manufacturer of the product. If the sensor is positioned for use as part of a security screening system, such as in an airport, the temporal sequence may be associated with a security company that manages the screening system.

While the use of a temporal sequence of colors may be implemented with one of the sensor arrangements described above, the invention is not limited to such an implementation. More generally, embodiments of the invention include the broad use of any temporal sequence of colors as an identifier of a product or service source. In some embodiments, such a temporal sequence of colors may additionally be coupled with a temporal sequence of sounds. The combination of the temporal sequences of colors and sounds effectively provides a brief musical light show that serves a branding function.

d. Use of Optical Detection Component

In addition to embodiments where the extended functionality of the biometric sensor is provided with only the illumination component, the extended functionality may also be provided with only the optical detection component of the

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sensor in other embodiments. In one such embodiment, the light detector comprised by the sensor is used as a light meter to quantify light levels. There are a number of applications for such a light meter that are within the scope of the invention, including use in photography applications, in ophthalmology applications, and as a meter for quantifying sun exposure, among others.

The collection of light with the detector also provides a means for collecting a small amount of energy from impinging photons. In such embodiments, the detector effective functions as a trickle charger when it is not in active use for identification and verification functions. The available of such trickle charging is especially useful in applications where battery lifetime is a paramount concern, notably in portable electronic devices such as cellular telephones. When the biometric sensor is incorporated into such a portable electronic device, its impact on battery lifetime is substantially mitigated by the use of trickle charging to recover battery lifetime that might be used in operating the sensor.

Having described several embodiments, it will be recognized by those of skill in the art that various modifications, alternative constructions, and equivalents may be used without departing from the spirit of the invention. Accordingly, the above description should not be taken as limiting the scope of the invention, which is defined in the following claims.

What is claimed is:

1. A device comprising:

a plurality of light sources, wherein at least two of the plurality of light sources provide light with distinct wavelengths;

a light detector, wherein the distance between the light detector and at least one of the plurality of light sources is different than the distance between the light detector and another of the plurality of the light sources; and

a processor configured to operate the light sources and the light detector to perform a plurality of distinct functions, wherein at least one of the distinct functions comprises a biometric identification function comprising:

propagating light from the plurality of light sources into presented material, and diffusely reflecting the propagated light toward the light detector;

receiving the diffusely reflected light with the light detector; and

identifying the presented material from the received light based on the wavelength characteristics of the received light and the distance between the source and the detector; and

wherein another of the distinct functions comprises a non-identification function performed with the light sources and the light detector.

2. The device recited in claim 1 wherein the light detector comprises a plurality of light detectors.

3. The device recited in claim 2 wherein the plurality of light detectors comprises an array of light detectors.

4. The device recited in claim 1 wherein the nonidentification function comprises a liveness function to determine whether the presented material is alive.

5. The device recited in claim 4 wherein the nonidentification function comprises operation of an optical switch having multistate functionality.

6. The device recited in claim 1 wherein the nonidentification function comprises a nonbiometric function.

7. The device recited in claim 6 wherein the nonidentification function comprises operation of an optical communications port with the light sources and the light detector.

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8. A portable electronic device comprising:
 an electronic arrangement for performing a standard function of the portable electronic device;
 a biometric sensor having:
 a plurality of light sources, wherein at least two of the plurality of light sources provide light at distinct wavelengths; and
 a light detector disposed relative to the light sources to detect light from the light sources that has propagated through tissue, wherein the distance between the light detector and at least one of the plurality of light sources is different than the distance between the light detector and another of the plurality of the light sources; and
 a processor configured to operate the electronic arrangement to perform the standard function and to operate the biometric sensor in accordance with the following:
 propagating light from the plurality of light sources into presented material, and diffusely reflecting the light toward the light detector;
 receiving the diffusely reflected light with the light detector; and
 identifying the presented material from the received light based on the wavelength characteristics of the received light and the distance between the source and the detector.

9. The portable electronic device recited in claim **8** wherein the electronic arrangement performs functions of a device selected from the group consisting of a cellular telephone, a personal digital assistant, an electronic fob, and a watch.

10. The portable electronic device recited in claim **8** wherein the processor is further configured to operate the biometric sensor to perform a nonbiometric function.

11. The portable electronic device recited in claim **10** wherein the nonbiometric function comprises a spectrometer function.

12. The portable electronic device recited in claim **11** wherein the spectrometer function is selected from the group consisting of a stress-detection function, a lie-detector function, a tanning-meter function, a complexion-monitor function, a toxicity-monitor function, an alcohol-monitor function, a bilirubin-monitor function, a hemoglobin-monitor function, a fruit-ripeness-monitor function, a counterfeit-document detection function, and a color-match function.

13. The portable electronic device recited in claim **10** wherein the nonbiometric function uses an illumination capacity of the plurality of light sources and uses a detection capacity of the light detector.

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14. The portable electronic device recited in claim **13** wherein the nonbiometric function is selected from the group consisting of an ambient-light-sensor function, an entertainment function, a personal-security function, a smoke-detector function, a motion-detection function, and an optical-strobe function.

15. The portable electronic device recited in claim **10** wherein the nonbiometric function uses an illumination capacity of the plurality of light sources.

16. The portable electronic device recited in claim **15** wherein the nonbiometric function is selected from the group consisting of an optical-ringer function, a flashlight function, and a laser-pointer function.

17. The portable electronic device recited in claim **10** wherein the nonbiometric function uses a detection capacity of the light detector.

18. The portable electronic device recited in claim **17** wherein the nonbiometric function is selected from the group consisting of a trickle-charger function and a light-meter function.

19. A device for performing a biometric function for presented material, the device comprising:
 a plurality of light sources arranged on a first side of the device, wherein at least two of the plurality of light sources provide light at distinct wavelengths;
 at least one light detector arranged on the first side of the device, wherein the distance between the light detector and at least one of the plurality of light sources is different than the distance between the light detector and another of the plurality of the light sources; and
 a processor configured to operate the light sources and the light detector to perform at least a first function and a second function,
 wherein first function comprises a biometric identification function comprising:
 propagating light from the plurality of light sources toward the presented material;
 diffusely reflecting the propagated light from the presented material toward the light detector;
 receiving the diffusely reflected light with the light detector; and
 identifying the presented material from the received light based on the wavelength characteristics of the received light and the distance between the source and the detector; and
 wherein the second function comprises a nonidentification function performed with the light sources and the light detector.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,620,212 B1
APPLICATION NO. : 10/640503
DATED : November 17, 2009
INVENTOR(S) : Jeffrey G. Allen et al.

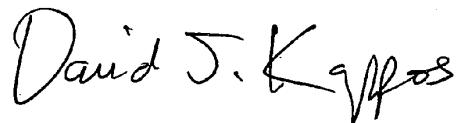
Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 24, line 5, delete “ophthalmology” and insert --ophthalmology--

Signed and Sealed this

Thirteenth Day of July, 2010

A handwritten signature in black ink that reads "David J. Kappos". The signature is written in a cursive, flowing style.

David J. Kappos
Director of the United States Patent and Trademark Office

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,620,212 B1
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DATED : November 17, 2009
INVENTOR(S) : Allen et al.

Page 1 of 1

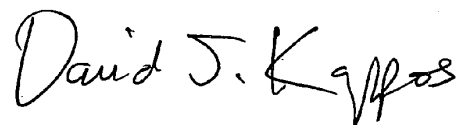
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page, Item [*]

Delete the phrase “by 963 days” and insert -- by 1631 days --.

Signed and Sealed this

Thirty-first Day of August, 2010

A handwritten signature in black ink, reading "David J. Kappos". The signature is written in a cursive, flowing style.

David J. Kappos
Director of the United States Patent and Trademark Office

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RX-0411.0035

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RX-0504

Optimization of Reflectance-Mode Pulse Oximeter Sensors

Austin Wareing, B.S.

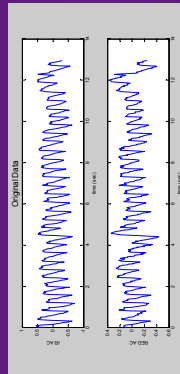
Sponsor: National Science Foundation Research Experiences for Undergraduates Program; Advisor: Steve Warren, Ph.D.

Pulse oximeters provide physiological information such as heart rate and blood oxygen saturation. These devices acquire measurements using red and infrared light that passes through the patient's skin and underlying tissue. Pulse oximeter sensors can either be transmission-mode, where light passes completely through the tissue and is collected on an opposing skin surface, or reflection-mode, where light is reflected back towards the sensor and collected in the same region as the incident light. Reflectance-mode sensors offer more measurement-site flexibility since they are only mounted on one side of the skin. However, these sensors are at a disadvantage since they collect only a fraction of the light reflected from tissue, which is primarily forward scattering. Increasing the reliability and quality of reflectance-mode signals will make these sensors a more attractive alternative to traditional transmission-mode designs.

Previous Design

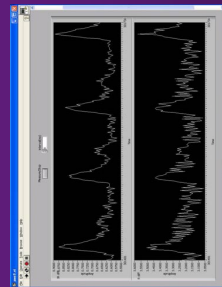
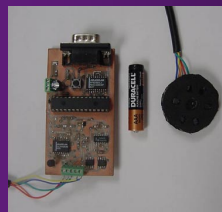


- One photodiode collects reflected red and infrared signals, resulting in poor efficiency and a smaller signal-to-noise ratio.
- Hard plastic material does not conform to most skin surfaces.
- More ambient light noise due to holes in plastic and inability to mold to a curved surface.



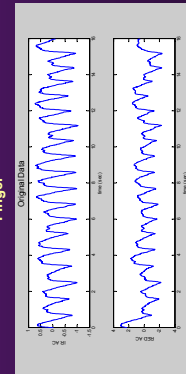
- Signal-to-noise ratio is highly dependent on sensor movement.
- Signal is often difficult to obtain, requiring several attempts to collect viable data.

Pulse Oximeter Sensor

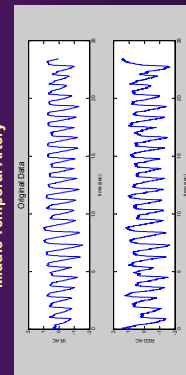


- Small, Lightweight components are unimposing to the wearer.
- Provides time-domain plethysmograms that can be used to calculate different physiological parameters.

Finger

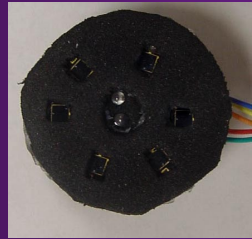


Middle Temporal Artery

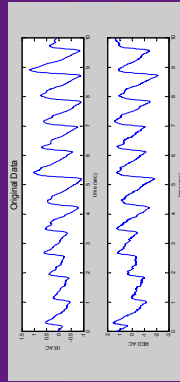


- Measurements from sites on the head are similar to those collected from sites on the finger.
- Head-mounted sensors have also proven to be less obtrusive since they do not impede movement or use of the hands.

Optimized Design

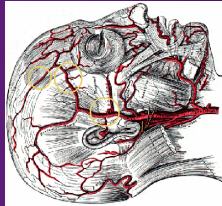


- Multiple photodiodes collect more of the reflected light, forming a radial pattern around the source(s).
- Pliable material allows the sensor to conform to the measurement site.
- Less susceptible to ambient noise due to opaque material and flexible design.



- Output signal exhibits greater signal-to-noise ratio.
- Signal is also more reliable than with the previous design; less effort is required to collect viable data.

Measurement Site Comparison



Viable and Unobtrusive Measuring Sites

- Middle temporal artery (in front of ear)
- Frontal branch (along hair line)
- Wrist



This material is based upon work supported by the National Science Foundation under grants BES-0440183 and BES-0093916. Opinions, findings, conclusions, or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the NSF.



Stimulating Student Learning with a Novel “In-House” Pulse Oximeter Design

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Abstract

This paper addresses the design of a plug-and-play pulse oximeter and its application to a biomedical instrumentation laboratory and other core Electrical Engineering courses. The low-cost, microcontroller-based unit utilizes two light-emitting diodes as excitation sources, acquires reflectance data with a photodiode, and sends these raw photo-plethysmographic data to a personal computer via an RS-232 serial link. A LabVIEW interface running on the personal computer processes these raw data and stores the results to a file. The design of this pulse oximeter is unique in two ways: the excitation sources are driven just hard enough to always keep the photodiode active (meaning the sensor can be used in ambient light), and the hardware separates out the derivatives of the red and infrared photo-plethysmograms so that it can amplify the pulsatile component of each signal to fill the range of the analog-to-digital converter. Unlike commercial pulse oximeters whose packaging hides the hardware configuration from the students, the open, unpackaged design stimulates student interest and encourages dialogue with the developer; the in-house nature of the design appeals to students. Moreover, most pulse oximeters on the market are expensive and provide users with a front panel that displays only percent oxygen saturation and heart rate. This low-cost unit provides unfiltered pulsatile data, allowing students to investigate tradeoffs between different oxygen saturation calculation methods, test different filtering approaches (e.g., for motion artifact reduction), and extract other biomedical parameters (e.g., respiration rate and biometric indicators). Time-domain data from these units have been used in linear systems and scientific computing courses to teach filtering techniques, illustrate discrete Fourier transform applications, introduce time-frequency principles, and test data fitting algorithms.

I. Introduction

An optical pulse oximeter measures the intensity of light passing through heterogeneous tissue and uses variations in this light intensity (primarily resulting from the fractional volume variation of arterial blood) to calculate blood oxygen saturation. Due to its non-invasive nature, high precision in its operational range, and reasonable cost, optical pulse oximetry is widely adopted as a standard patient monitoring technique. Although its foundations date back more than fifty years,¹ many facets of this technology still attract researchers. Current interest areas include motion artifact reduction,^{2,3} power consumption optimization,⁴ low-perfusion measurements,^{5,6} and issues germane to various application environments (e.g., wearability for battlefield and home care monitors).⁷⁻⁹ It is important for biomedical engineering students to understand the principles of pulse oximetry, hardware/software design issues, and signal processing approaches.

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Pulse oximeter design addresses engineering areas such as optical component selection, mechanical layout, circuit design, microprocessor control, digital communication, and signal processing. Therefore, a pulse oximeter not only serves as an excellent study vehicle that allows students to learn techniques such as photoplethysmographic signal processing; it also provides a platform where students can acquire hands-on experience in practical device design. In addition, the real-time data that a pulse oximeter offers gives instructors flexibility when assigning projects and homework to students of various educational levels (graduate and undergraduate) and backgrounds (e.g., electrical engineering or biology).

Many commercial pulse oximeters display calculated parameters (i.e., percent oxygen saturation and heart rate) on their front panels, hiding the original unfiltered data from which these calculations were made. In this paper, we present an “in-house” pulse oximeter that provides raw sensor data for use in the classroom. The device is utilized in bioinstrumentation laboratory sessions, and its data provide real-world signals to other core Electrical Engineering courses.

This paper first briefly describes the theory behind photoplethysmographic (PPG) pulse oximetry. It then presents the development of a pulse oximeter, emphasizing design features that enable its application to education. These features include (a) a stand-alone pulse oximeter module with a novel circuit design, an open form-factor, and multiple signal outputs, (b) a personal computer station with a flexible, user friendly LabVIEW interface and a variety of signal processing options, and (c) the production of raw data that can be used for parameter extraction exercises. The paper describes how this device and its features have been applied in classroom environments to stimulate student learning. Several examples are introduced in detail, including (a) a pulse oximetry laboratory/lecture pair for a bioinstrumentation course sequence, (b) data sources for course projects in Linear Systems (EECE 512) and Scientific Computing (EECE 840), and (c) a platform upon which undergraduate honors research students can build. This approach can be extended to other devices and classes.

II. Theory – Principles of Pulse Oximetry

PPG pulse oximetry relies on the fractional change in light absorption due to arterial pulsations. In a typical configuration, light at two different wavelengths illuminating one side of tissue (e.g., a finger) will be detected on the same side (reflectance mode) or the opposing side (transmission mode) after traversing the vascular tissues between the source and the detector.¹⁰ When a fingertip is simplified as a hemispherical volume that is a homogenous mixture of blood (arterial and venous) and tissue, the detected light intensity is described by the Beer-Lambert law:¹¹

$$I_t = I_0 \left(e^{-\mu_{at}T} \right) \left(e^{-\mu_{av}V} \right) \left(e^{-\mu_{aa}A} \right) \quad (1)$$

where I_0 is the incident light intensity, I_t is the light intensity detected by the photodetector, and μ_{at} , μ_{av} , and μ_{aa} are the absorption coefficients of the bloodless tissue layer, the venous blood layer, and the arterial blood layer, respectively, in units of cm^{-1} .

The heart's pumping action generates arterial pulsations that result in relative changes in arterial blood volume, represented by dA , which adds an “ac” component to the detected intensity:

$$dI_t = -I_0 \mu_{aa} \left(e^{-\mu_{at}T} \right) \left(e^{-\mu_{av}V} \right) \left(e^{-\mu_{aa}A} \right) dA \quad (2)$$

Multiple elements contribute to the attenuation of light traveling through tissue, and arterial pulsation has only a small relative effect on the amount of light detected (on the order of one percent or less; see Figure 1).

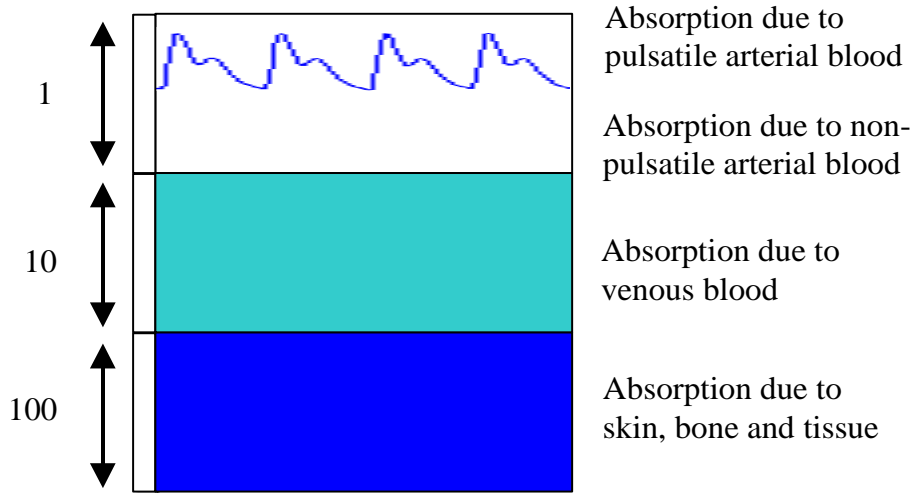


Figure 1. Breakdown of the components in the detected photo-plethysmographic signal.¹²

Dividing this change by the dc value normalizes this variation:

$$\frac{I_{ac}}{I_{dc}} = \frac{dI_t}{I_t} = -\mu_{aa} dA \quad (3)$$

The ratio of the above ratio for two wavelengths ('r' for red, 'IR' for infrared) is given by

$$R = \frac{(dI_t / I_t)_r}{(dI_t / I_t)_{IR}} = \frac{\mu_{a,r}}{\mu_{a,IR}}, \quad (4)$$

where $\mu_{a,i}$ can be expressed as a function of $S_a O_2$,¹³ arterial oxygen saturation:

$$\mu_{a,i} = \frac{H}{v_i} [S_a O_2 \sigma_a^{100\%} + (1 - S_a O_2) \sigma_a^{0\%}] \quad (5)$$

Here, $i = r, IR$, while $\sigma_a^{100\%}$ and $\sigma_a^{0\%}$ are the wavelength-dependent optical absorption cross sections of the red blood cells containing totally oxygenated and totally deoxygenated hemoglobin, respectively. One can therefore calculate arterial oxygen saturation using

$$S_a O_2 = \frac{R \sigma_{a,IR}^{0\%} - \sigma_{a,r}^{0\%}}{(\sigma_{a,r}^{100\%} - \sigma_{a,r}^{0\%}) + R(\sigma_{a,IR}^{0\%} - \sigma_{a,IR}^{100\%})} \quad (6)$$

Equation (6) provides the desired relationship between the experimentally-determined ratio R and the arterial oxygen saturation $S_a O_2$. Researchers assume this relationship applies to monochromatic light sources. In reality, commonly available LEDs are used as light sources and typically have spectral widths of 20 to 50 nm. Therefore, the standard molar absorption coefficient for hemoglobin cannot be used directly in (6). Furthermore, the simplified mathematical description above only approximates a real system that incorporates

inhomogeneities and mechanical movement. Consequently, (6) is often represented empirically by fitting clinical data to the following generalized function:

$$S_a O_2 = k_1 R + k_2 \quad (7)$$

where, e.g., $k_1 = -25.6$, $k_2 = 118.8$ ¹⁴ or $k_1 = -25$, $k_2 = 110$.¹⁵

III. Methods

A. Pulse Oximeter Development

As shown in the functional block diagram in Figure 2, a pulse oximeter consists of three main units: (1) an optical probe, (2) a circuit module that hosts an analog amplifier, signal conditioning element, and microcontroller, and (c) a personal computer that receives data from the circuit module and processes, displays, and stores these data.

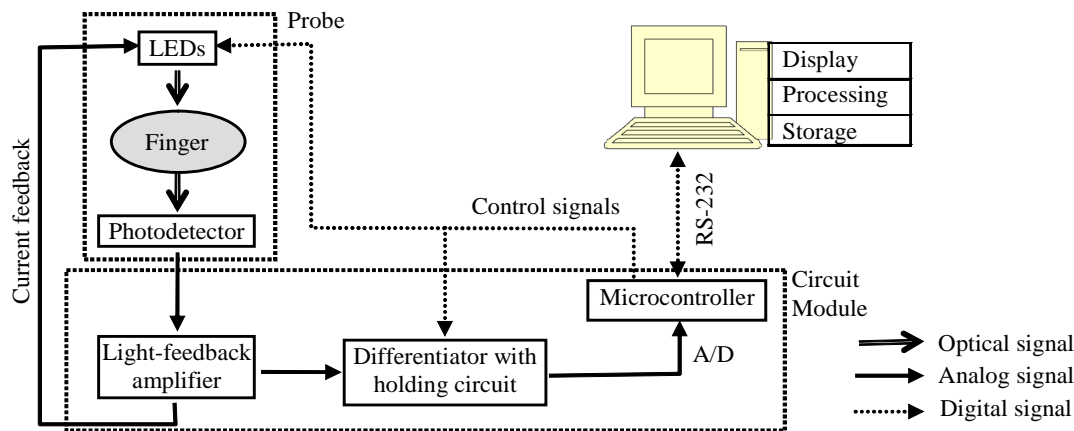


Figure 2. Functional block diagram of the pulse oximeter.

The analog portion of the pulse oximeter consists of a light-feedback amplifier and an analog differentiator with a specialized sample and hold circuit. The current feedback design adjusts the light level at the excitation LEDs such that the detected light intensity is constant, keeping the photodiode centered in its active region. To improve the stability of this feedback loop, a photodiode with smaller gain, rather than a phototransistor, is used as a photodetector. Two LEDs with wavelengths of 660 nm and 940 nm were selected as excitation sources.

As discussed earlier, the “ac” component resulting from arterial blood volume variation is very small. If A/D conversion is performed on the overall signal, this tiny “ac” component will be buried in the “huge” “dc” component after conversion. A differentiator addresses this issue. It removes the “dc” component by subtracting the previous signal voltage-level from the present signal voltage-level and amplifies this difference, yielding the “ac” component. A hold circuit is added to store voltage-levels from the previous sample cycle. The differentiator improves signal resolution by allowing one to take advantage of the full range of the A/D converter.

This circuitry is coordinated by a PIC microcontroller. Three output lines control the operation of the circuitry, and two A/D inputs sample the desired signal. Two outputs modulate the two light sources and switch the charging and discharging of their corresponding hold capacitors. The

other output operates the differentiator. The two A/D inputs acquire and digitize two signals: the “dc” signal when the differentiator is turned off (it is actually the original signal that includes both “dc” and “ac” components) and the amplified difference of the present and previous voltage level when the differentiator is turned on.

The PIC microcontroller also operates an RS-232 port to a personal computer running a LabVIEW interface. Digitized data are sent to the PC over this RS-232 interface. Because the sensor module and personal computer communicate asynchronously, and 8 bytes (two bytes for each signal) are sent in each RS-232 packet, a handshaking protocol is used to synchronize the two devices. The PC generates an acknowledgement after successfully receiving each data packet so that the pulse oximeter module can transmit the next data packet.

On the PC, LabVIEW virtual instruments (a) reconstruct the differentiated data, (b) filter the pulsatile signal with motion artifact reduction algorithms, (c) display the differentiated and reconstructed waveforms, (d) compute and display values for heart rate and blood oxygen saturation (see Figure 4), and (e) store the original and processed data to a text file for follow-up analysis. The data in the file are in columnar format:

- Column 1 – Time in milliseconds,
- Column 2 – $d(I_{ac})_{ir}/dt$ (derivative of the near-infrared signal)
- Column 3 – $(I_{dc})_{ir}$
- Column 4 – $d(I_{ac})_{red}/dt$ (derivative of the red signal)
- Column 5 – $(I_{dc})_{red}$
- Column 6 – $(I_{ac})_{ir}/dt$ (reconstructed near-infrared signal)
- Column 7 – $(I_{dc})_{red}$ (reconstructed red signal)

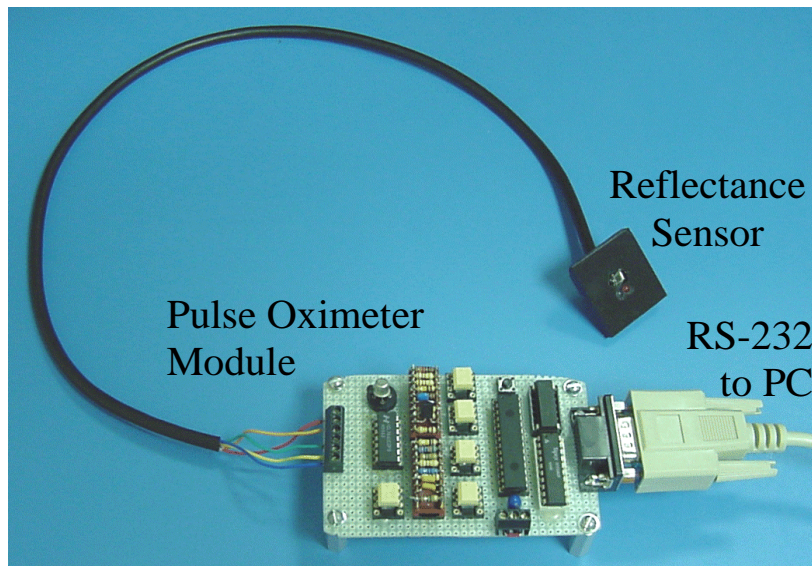


Figure 3. Pulse oximeter module and reflectance probe.

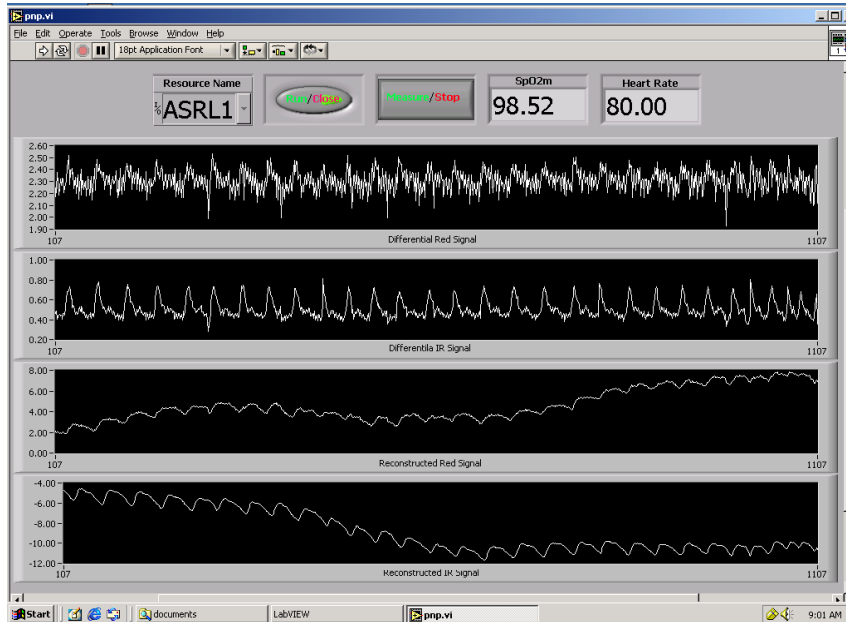


Figure 4. LabVIEW virtual instrument for the pulse oximeter. In addition to heart rate and blood oxygen saturation (%), the interface displays the red and infrared derivative data (top two waveforms) and the red and infrared reconstructed data (bottom two waveforms).

B. A Pulse Oximetry Lecture/Laboratory Pair

At Kansas State University, the 4-credit-hour Bioinstrumentation course sequence (URL: <http://www.eece.ksu.edu/~eece772/>) consists of three courses instructed by faculty from the Department of Electrical & Computer Engineering (EECE) and the Department of Anatomy and Physiology (AP). These courses are EECE 772 (Theory and Techniques of Bioinstrumentation, 2 hours), EECE 773 (Bioinstrumentation Design Laboratory, 1 hour), and AP 773 (Bioinstrumentation Laboratory, 1 hour). These courses can be taken for either undergraduate or graduate credit. The two laboratory hours provide hands-on experience and are intended to help students obtain a deeper understanding of concepts learned in lectures.

The pulse oximeter discussed earlier serves as a basis for a lecture/laboratory pair in the Bioinstrumentation course sequence. In order to improve the quality of the laboratory, the second author designed a laboratory session for AP 773 that uses the pulse oximeter developed by the first author. Four sets of devices were constructed and have been used as teaching tools in these laboratory sessions. The **learning objectives** of this laboratory (i.e., what a student should be able to do upon completion of the laboratory) are the following:

- Explain the physiological origin of a photoplethysmogram
- Describe the hardware and software components required to determine blood oxygen saturation using light-based sensors
- Calculate blood oxygen saturation given a set of red/infrared plethysmograms
- Assess the character and spectral content of the time-varying signals

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- Extract physiological data from a photoplethysmogram
- Describe person-to-person variations in plethysmographic signal data
- Calculate calibration coefficients using different approaches
- Counteract the effects of mild motion artifact

During the laboratory, the class is divided into groups of 2~3 students. Each group is equipped with a collection of components: a reflectance probe, a circuit module, a serial cable, and a personal computer with the LabVIEW interface installed. The students are first taught how to use the modules properly. They then gather PPG data from their team members at different body locations and save these data to files for later signal processing.



Figure 5. Two students acquire photoplethysmographic data in the AP 773 pulse oximetry laboratory (Fall 2002).

These data are processed using Microsoft Excel or MATLAB. In addition to observing and analyzing time domain data, the students are also required to interpret and understand the spectral components of the signal by performing Fast Fourier Transforms (FFTs) on the data sets. They implement different methods for calculating the “ac/dc” ratios required to obtain arterial oxygen saturation. Two calculation methods are used to compute these ratios. The methods correspond to Equations 3 and 4, which supply a parameter for Equation 7. The ‘peak/valley’ method considers the peak-to-valley amplitude of the reconstructed signal as I_{ac} when calculating the “ac/dc” ratio. This method is evaluated with two different filtering techniques: a sliding average filter and a sliding median filter. The FFT method uses the spectral peaks of the red and near-infrared signals to represent I_{ac} in the calculations. The students are then asked to compare the calculation methods and choose the best one.

Students are also encouraged to experiment with other noise reduction filters. Additionally, by observing and analyzing waveforms acquired from different team members, students can realize that factors such as skin color and perfusion affect the quality of acquired PPG data. They are also asked to evaluate the differences between PPG signals acquired at different body locations (e.g., wrist, forehead, or ear lobe) that have noticeably different vascular profiles.

C. Pulse Oximeter Applied to Other Educational Venues

In addition to the lecture/laboratory pair noted in the previous section, the pulse oximeter design and the signal data gathered from various implementations of this design have been applied in multiple undergraduate (*EECE 499 – Honors Research; EECE 512 – Linear Systems*) and graduate (*EECE 840 – Scientific Computing*) educational venues. The **signals** acquired from this platform have been used in the following ways:

- data for time-domain smoothing algorithms (see Figure 6),
- signals for time- and frequency-domain filtering projects (see Figure 7 and Figure 8),
- waveforms for Fourier series reconstruction projects (see Figure 9), and
- signals for time-frequency spectrogram projects (see Figure 10).

The **modules** have also been used as starting points for various undergraduate honors research projects, as depicted in Figure 11.

Course Projects. In the smoothing exercises (see Figure 6), students are asked to perform signal processing exercises to ‘smooth out’ variations in signals corrupted with noise. Two of the common techniques are illustrated here. Polynomials, by their nature, are smooth curves whose numbers of peaks and valleys correspond to the order of the polynomial. In this figure, a polynomial of order 12 provides a reasonable representation of the original data set. Note that the behavior of the fitting polynomial is unpredictable outside of the original bounds. Sliding average and median filters are also a smoothing approach that can be implemented by a young student without much programming experience (the graph on the right in Figure 6 was produced with an Excel spreadsheet). For this photoplethysmograph (sampled at 160 Hz), a 7-wide sliding window appears to provide a reasonable job of smoothing out the noise while retaining the fundamental shape of the waveform.

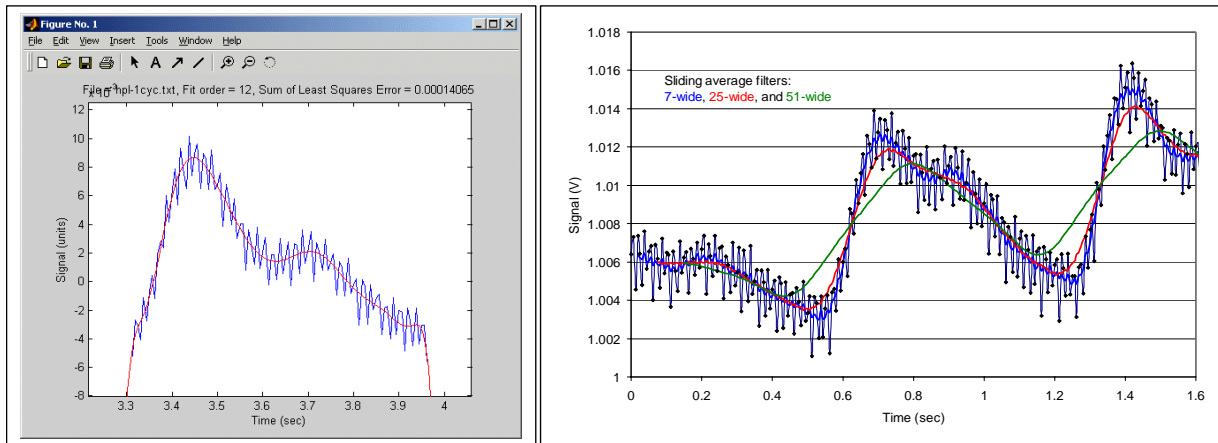


Figure 6. Data smoothing algorithms (polynomial fits and sliding average filters) applied to photoplethysmographic data. These exercises were assigned in EECE 772 (Bioinstrumentation) and EECE 840 (Scientific Computing).

In the EECE 512 project depicted in Figure 7, a student’s code (1) loads a signal from an input ASCII text file, (2) performs a convolution (i.e., filtering operation) between the input signal and a cascade of 2nd-order Butterworth lowpass and highpass filters (which can be combined to create lowpass, highpass, or bandpass filters), (3) saves the output signal to disk, and (4) plots the original and filtered signals to the screen. Input signals for these simulations include both ideal

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signals (e.g., pulses, square waves, and sinusoids) and real-world signals (e.g., biomedical signals such as electrocardiograms and light reflectance signals from the pulse oximeter modules presented here).

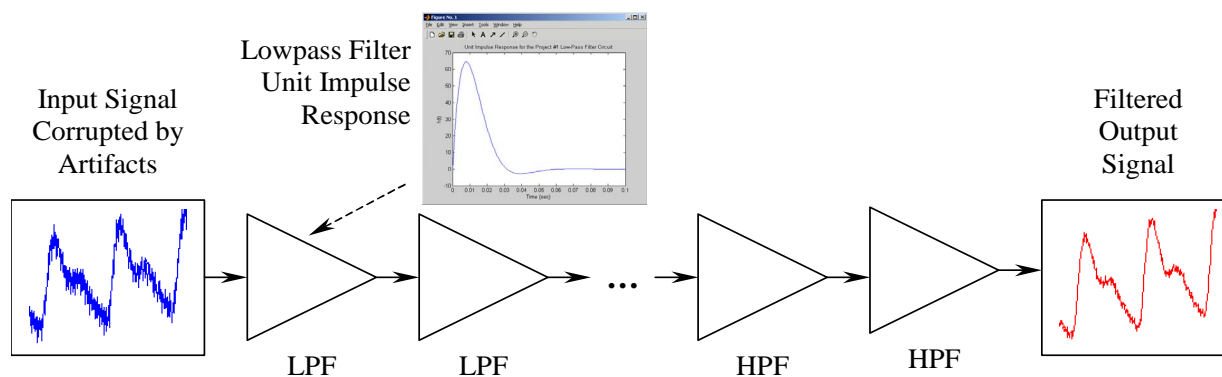


Figure 7. Multi-stage filtering of photoplethysmographic data via time-domain convolution in EECE 512 (Linear Systems). Stages: 2nd-order lowpass and highpass filters.

Frequency-domain filters are also an important part of a signals and systems course. In these projects, a student's program typically (1) loads an input signal from a file and calculates its Fourier transform, (2) calculates the frequency response of a filter chosen by the user, and (3) performs a frequency-domain filtering operation on the input signal: it multiplies the input signal spectrum by the spectrum of the filter and then takes the inverse Fourier transform of the result. The program then saves the input/output signals, their spectra, and the filter spectra to a set of ASCII text files and creates a plotting script that can be called by MATLAB or GNUPLLOT. In the example illustrated in Figure 8, an ideal bandpass filter with a low cutoff of 0.3 Hz and a high cutoff of 15 Hz was used to remove the drift and 60 Hz noise present in the original plethysmographic signal.

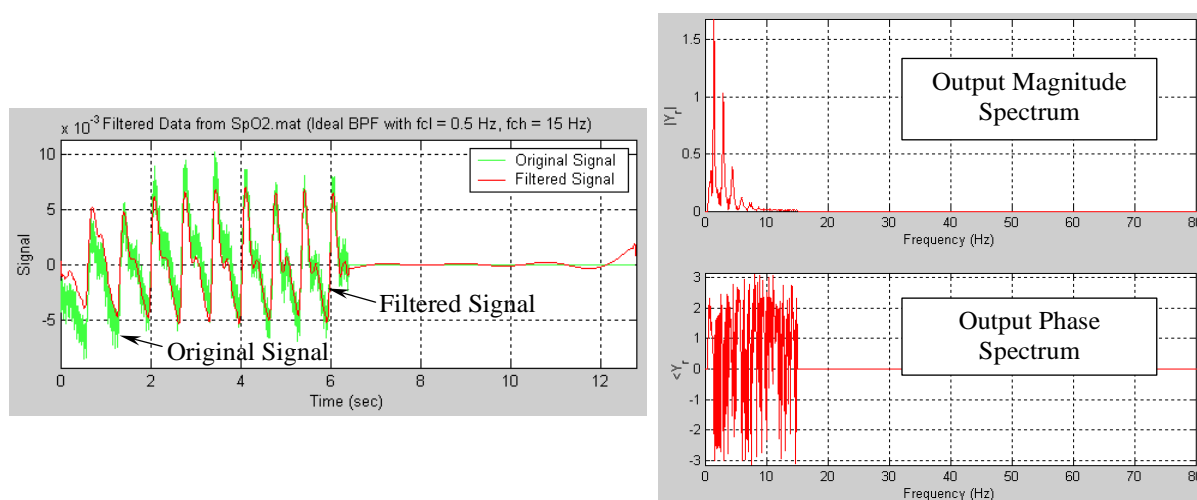


Figure 8. Frequency-domain filtering of pulsatile light reflectance data to remove signal drift and 60 Hz noise. Course: EECE 512 (Linear Systems).

Figure 9 illustrates the use of light reflectance signals in a Fourier series project. In the left part of Figure 9, the top set of axes displays a PPG signal and its Fourier series reconstruction. The middle and bottom axes plot the magnitude and phase coefficients, respectively, that were calculated for the reconstruction. Note that 45 harmonics (or cosines with different magnitudes and phases) were required to replicate the shape of the initial signal. In the canine electrocardiogram depicted on the right hand side of the figure, 125 harmonics produced a good reconstruction. This is due to the higher frequency components present in each QRS complex.

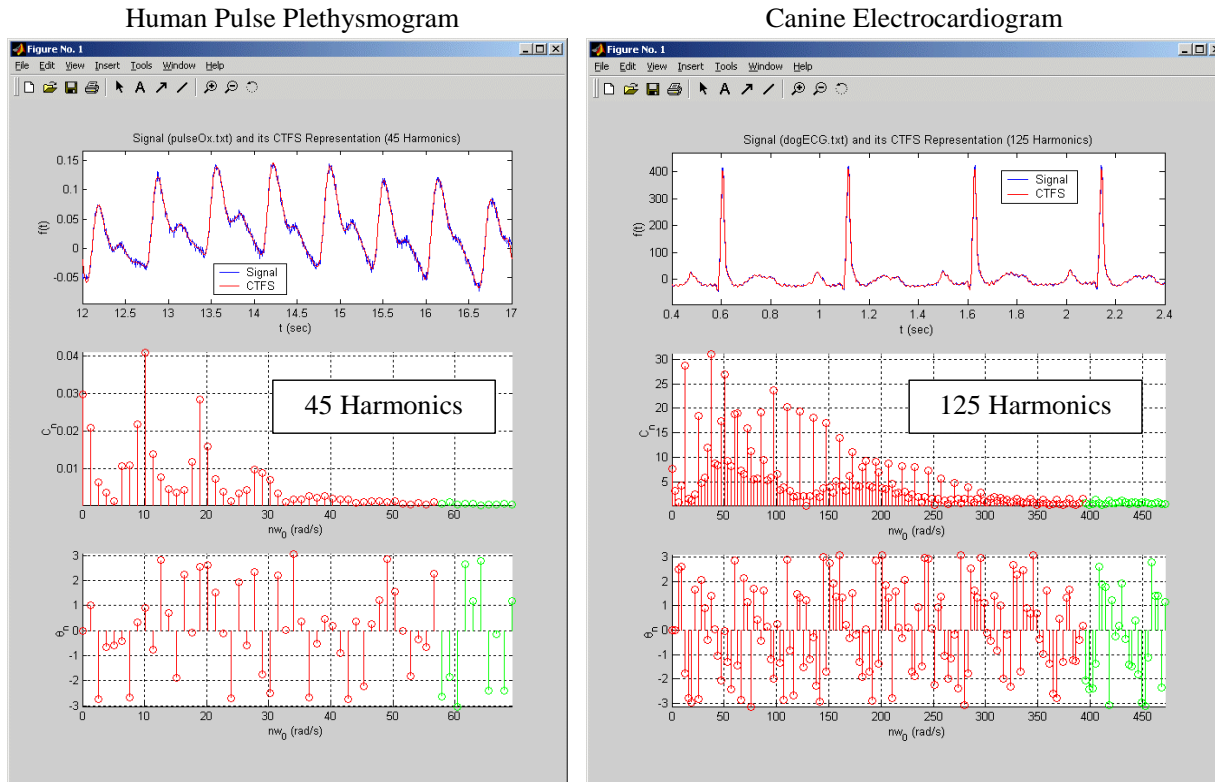


Figure 9. Reconstruction of biomedical signal data (human finger photoplethysmogram and canine electrocardiogram) using Fourier series. Class: EECE 512 (Linear Systems).

It can be helpful to understand how a signal's spectral character changes as a function of time. Figure 10 presents an example of a MATLAB interface that would be written by a student in a graduate scientific computing course. In this figure, the upper left set of axes plots the time-domain plethysmogram, while the lower left set of axes displays the spectrum of the signal versus time. The plots on the right depict the magnitude and phase spectrum of the input signal at the time denoted by the vertical line that occurs at ~55 seconds (see the upper left trace). The fields on the right side of the interface depict parameters that can be chosen by the user.

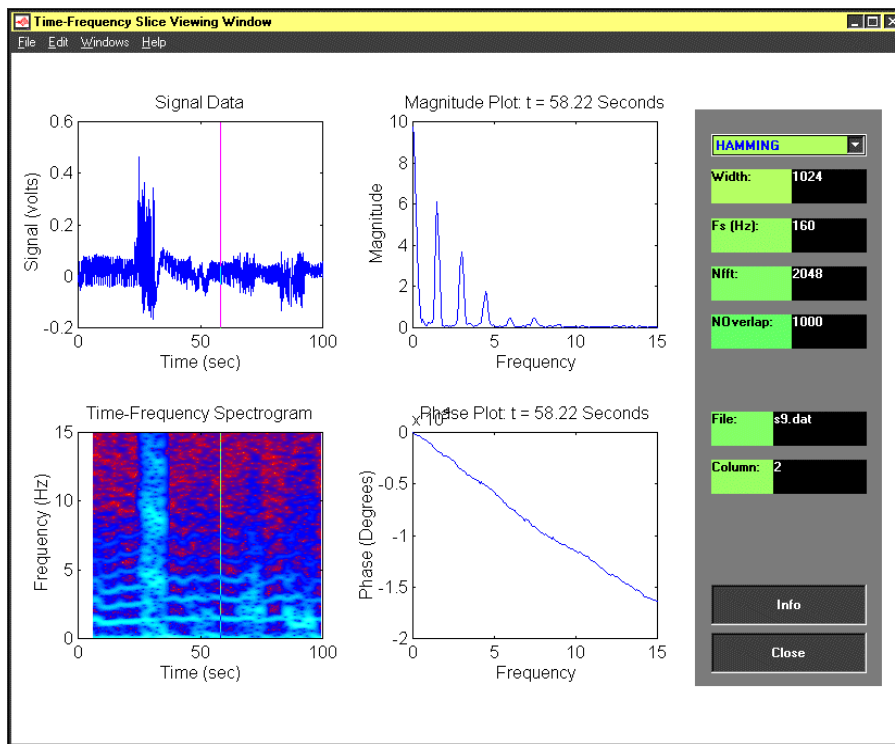


Figure 10. Time-frequency analysis of reflectance data in EECE 840 (Scientific Computing).

Honors Research Projects. The undergraduate Electrical & Computer Engineering curriculum at KSU allows high achieving students to perform research for course credit. The pulse oximeter modules presented in this paper have contributed to five EECE 499 (Honors Research) projects to date (see Figure 11). For the project shown at the top of the figure, Ben Young developed a system based upon the pulse oximeter module that acquired light reflectance data from the forehead using sensors mounted on a firefighter helmet. The goal of this project was to establish whether meaningful blood oxygen saturation measurements could be acquired continuously on an individual that needed to use their hands freely and could be exposed to dangerous levels of carbon monoxide. The second project from the top, managed by Shelly Allison and Craig Nelson, involved gathering light reflectance data from normal and hypertensive elderly subjects. These data will be analyzed for correlations between spectral behavior and the measured blood pressure of the subjects. The goal is to find a comfortable, noninvasive way to replicate the information normally provided by often painful blood pressure cuffs.

As noted in Figure 11, Jonathan Hicks investigated a method to use a patient's light reflectance data as a biometric indicator. This capability would allow a home monitoring system to authenticate the identity of a patient prior to uploading the patient's physiological data to a remote electronic patient record. The benefits of this approach are two-fold: (1) no interaction is required on the part of the patient and (2) the data are independently verified prior to submission. The plots in Figure 11 show a representative light reflectance signal for a patient and the single-period template used to represent that time-varying signal. Two other representative templates are also depicted in the figure to show how these wave shapes vary from person to person. This

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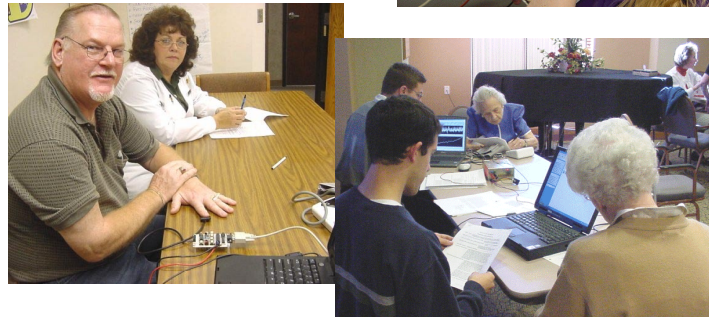
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method uses a statistical test to determine whether a patient's current data are similar to the single-period template stored for the patient. Finally, Austin Wareing was supported by an NSF Research Experience for Undergraduates grant to optimize the light reflectance sensor design and improve the interaction between the pulse oximeter and the host LabVIEW program. His radial sensor design and a resulting set of waveforms are depicted at the bottom of Figure 11.

Ben Young: Forehead Measurements of Blood Oxygen Saturation for Use with Fire Fighter Helmets



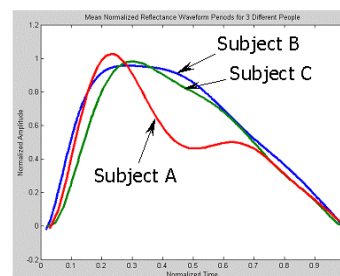
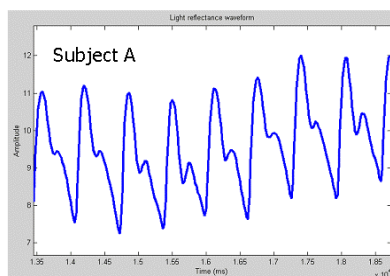
Shelly Allison and Craig Nelson: Light-Based Indicators for Hypertension



Jonathan Hicks: Photoplethysmographic Signals as Biometric Authenticators

Multi-Period Light Reflectance Waveform

Single-Period Light Reflectance Templates



Austin Wareing: Optimization of Light Reflectance Sensors

Pulse Oximeter Module

Reflectance Data from the Thumb

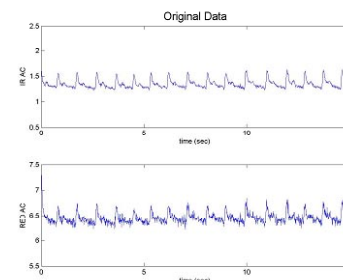
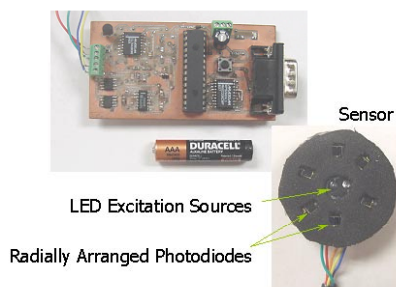


Figure 11. Honors research projects that have benefited from the pulse oximeter design.

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IV. Discussion and Conclusion

This paper presented initial efforts to apply an in-house pulse oximeter design to multiple secondary education venues. These efforts have indicated that students enjoy instructional experiences that utilize real-world devices, especially when they can manipulate elements of the design such as the signal processing algorithms that would normally be hidden from the user. The pulse oximeter modules have been used in four Fall offerings of the AP 773 laboratory (2001~2004). Because these home-grown pulse oximeters offer improved data access as compared to commercial products, instructors can experience far greater flexibility when assigning homework, which is especially appreciated when the background and educational experiences of the students vary significantly.

Each laboratory session that utilized these modules has been supported by device developers. Interactions between the device developers and the students (users) lead to experiences that are hard to replicate with packaged, off-the-shelf units. These interactions help the students appreciate the concepts discussed in lecture and allow them to become more familiar with the device development process.

As noted in the body of the paper, several other undergraduate and graduate courses have benefited from the data availability offered by these pulse oximeters. When asked, “What part of the project did you like the most” (on the survey for the Spring 2003 Linear Systems project depicted in Figure 7) one student responded, “Being able to see the ECG and pulse oximeter signals with the noise filtered out.” Many other individuals in this class of 65 students had similar opinions about working with data provided by a device in a nearby laboratory. Processing real-world signals stimulated the students’ interest the most, followed by the excitement of simply getting their code to work. The same Linear Systems student, when asked the question, “How could a project of this nature be improved?,” responded with, “More realistic signals to filter – that is what made me feel like this was a realistic project.”

The inexpensive hardware, plug-and-play features, and information-rich signals offered by these pulse oximeters have also provided starter platforms for honors students that wish to perform innovative research. These experiences not only help them to apply knowledge learned from their courses and understand recent developments; more importantly, they may also motivate these capable students to pursue careers in an expanding biomedical industry.

Acknowledgements

The authors wish to acknowledge Jerry T. Love, Sandia National Laboratories (retired), for the original design of the light feedback circuit. Portions of this material are based upon work supported by the National Science Foundation under grant BES-0093916. Opinions, findings, conclusions, or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the NSF. All studies addressed in this paper that involve human subjects have been approved by the Human Studies Board at Kansas State University under protocol #2211.

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Biographical Information

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RX-0670

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United States Patent [19]

[11] 4,224,948

Cramer et al.

[45] Sep. 30, 1980

[54] WRIST BORNE PULSE
METER/CHRONOMETER[76] Inventors: Frank B. Cramer, 14800 Alexander
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Lawrence Semar, 17422 Village Dr.,
Tustin, Calif. 92680

[21] Appl. No.: 963,278

[22] Filed: Nov. 24, 1978

[51] Int. Cl.³ A61B 5/02

[52] U.S. Cl. 128/690

[58] Field of Search 128/687-690,
128/698, 705-706, 708; 324/78 D, 186;
364/701-702, 715-717

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Primary Examiner—Robert W. Michell

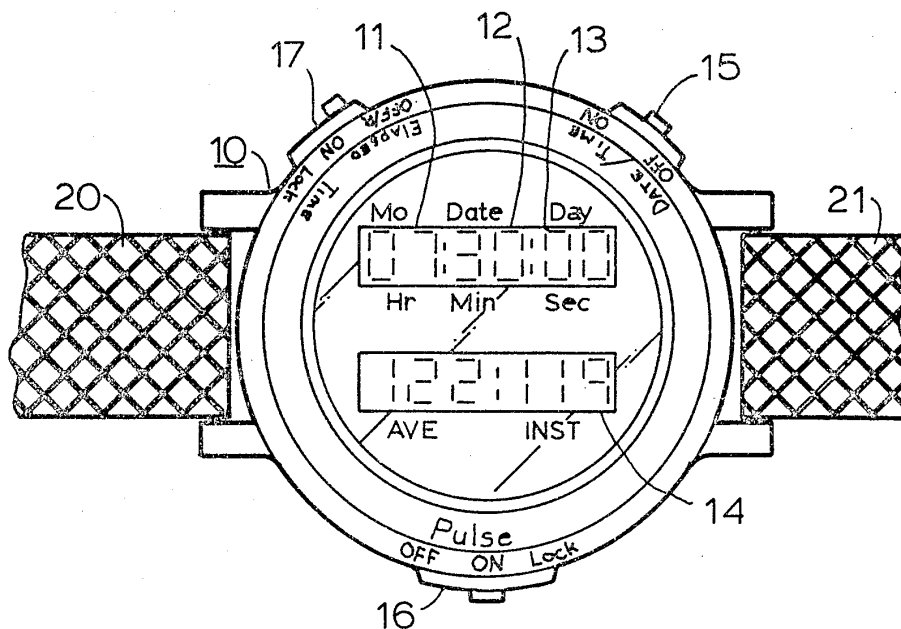
Assistant Examiner—Francis J. Jaworski

Attorney, Agent, or Firm—John E. Wagner

[57] ABSTRACT

A combined watch, elapsed time counter and pulse rate meter which is totally portable and worn as an ordinary wristwatch. The timer and pulse rate meter employ the precise timing elements such as a crystal oscillator of the digital watch. Using such precise timing elements, the human's pulse may be measured on a pulse by pulse basis and the instantaneous and average pulse values simultaneously displayed to allow a running comparison and noting of pulse aberrations. A novel pulse detector assembly is located on the inner face of the watch assembly.

15 Claims, 9 Drawing Figures



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FIG. 1

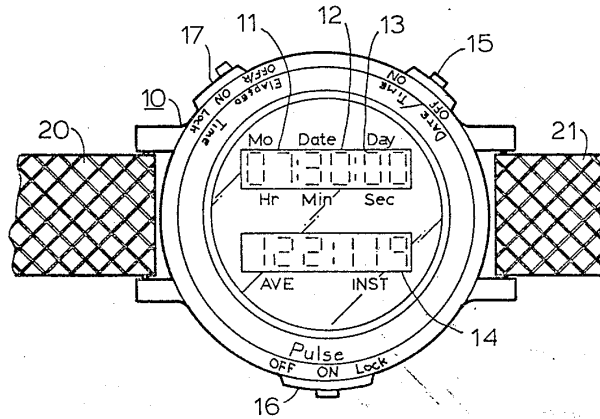


FIG. 9

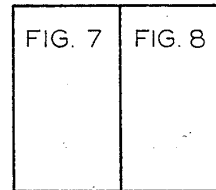


FIG. 6

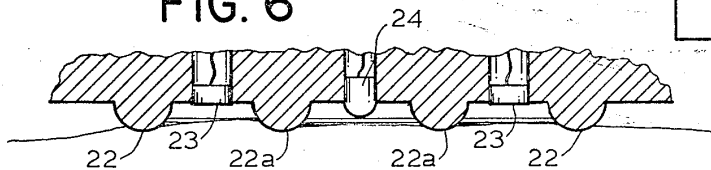


FIG. 2

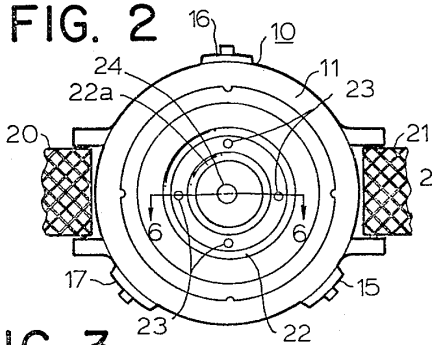


FIG. 4

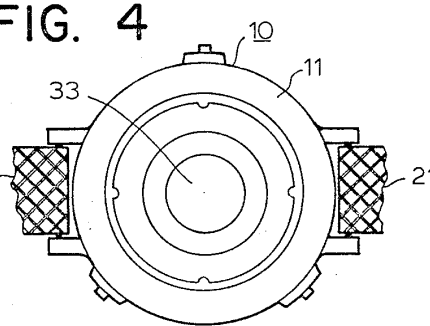


FIG. 3

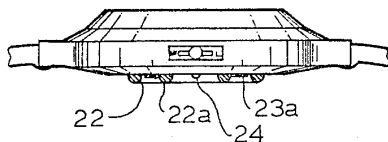


FIG. 5

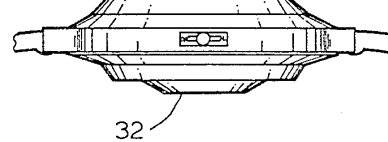
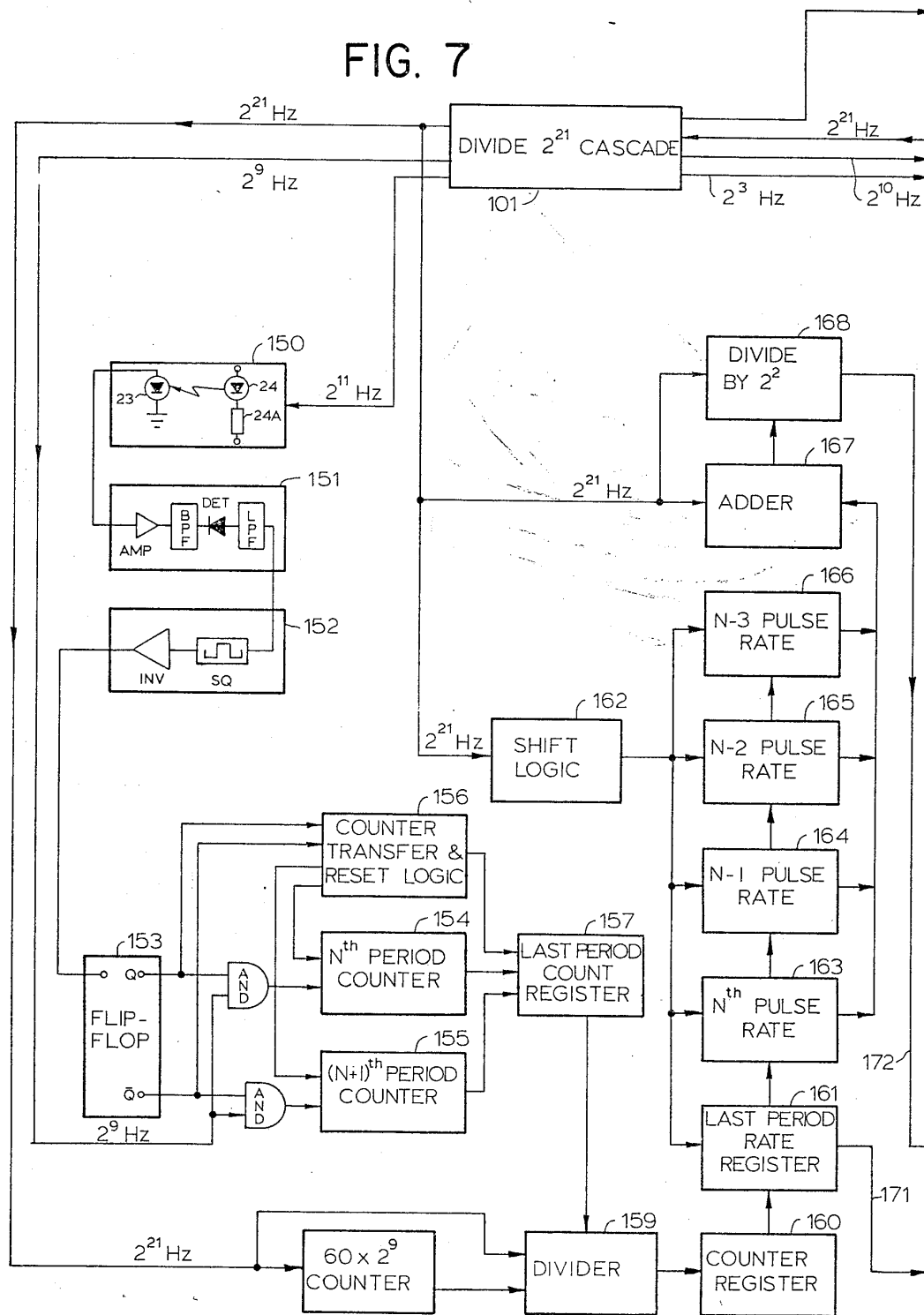


FIG. 7

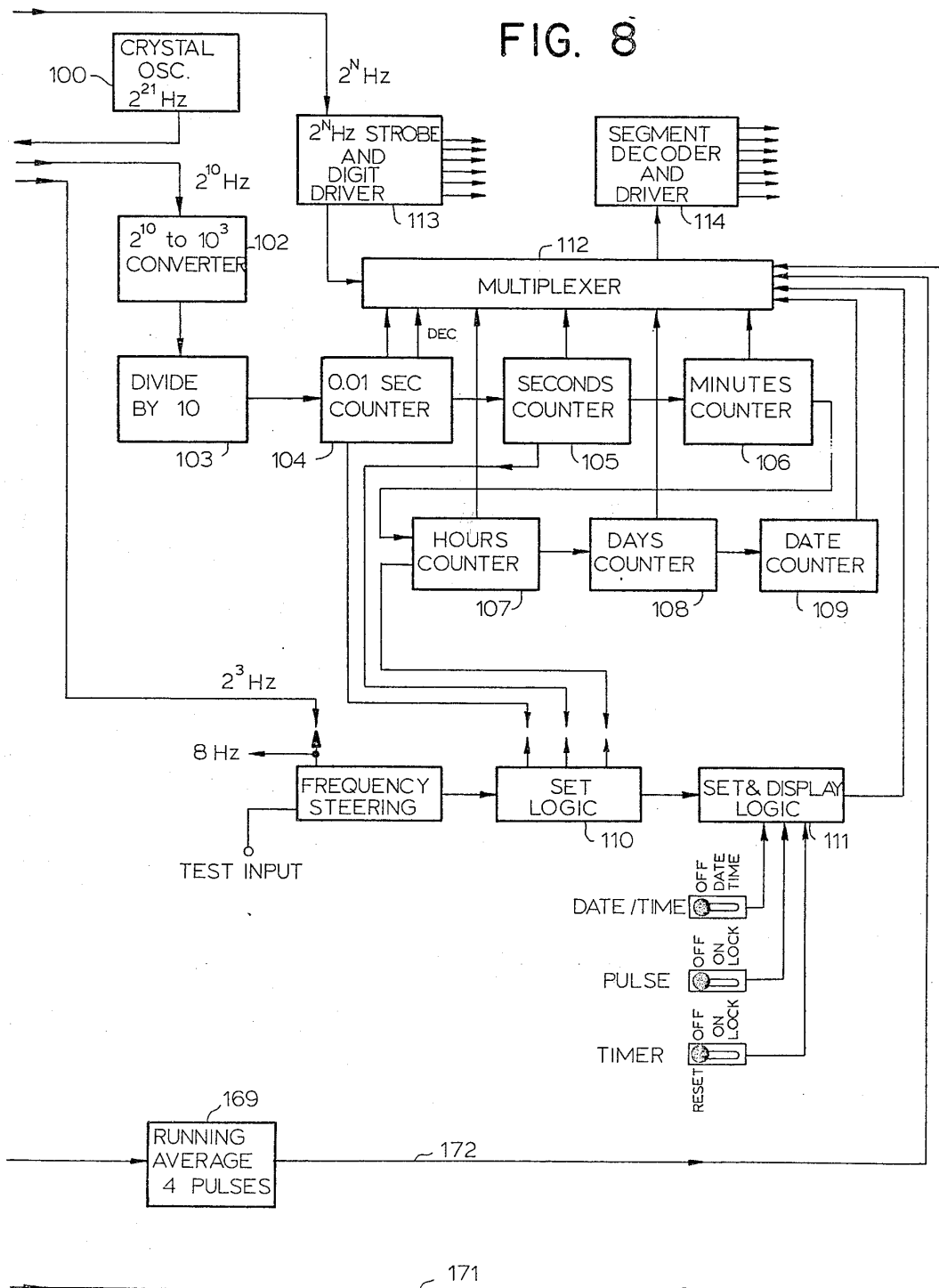


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FIG. 8



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WRIST BORNE PULSE METER/CHRONOMETER**BACKGROUND OF THE INVENTION**

For many years both health care professionals and athletic coaches have recognized that the pulse rate of an individual is a primary source of information about the current and long-term condition of a person's physiology. To the health care professional the measurement of pulse rate is a primary measurement taken at the outset of an examination and is a parameter which is measured regularly for continuing diagnosis and care. Hospitals are now well equipped for continuous monitoring of the pulse rate of patients in cardiac and critical care units. To the athletic coach and to the occasional and regular athlete, the pulse rate of the athlete is important and hopefully known. In the past attempts have been made to produce a portable pulse rate meter which can be carried by or worn by the athlete to provide current pulse rate information while the athlete is engaged in strenuous activity such as running. Examples of patents showing pulse rate meters to be worn or carried by individuals are U.S. Pat. Nos. 3,978,849 to Harold S. Geneen, 4,009,708 to John J. Fay, Jr., 4,058,118 to Lawrence J. Stupay et al, 4,030,483 to Jack B. Stevens, 4,063,551 to James Sweeney, and 4,038,976 to Frank M. Hardy et al.

Numerous other patents have issued to inventors of complex pulse rate meters designed for non-portable hospital and other fixed installation use. Examples of such equipment are shown in U.S. Pat. Nos. 4,022,192 to Laukren and 4,018,219 to Hajaiban.

Numerous patents have issued on digital watches and various timing and display circuitry therefor.

Nowhere in the prior art has it been recognized that by combining a pulse rate meter with a digital watch, in addition to the normal advantages one might expect, the resulting instrument has greater contribution than the sum of its parts. It is believed that in the prior art no one has combined a watch giving real time with a pulse-rate meter. And more particularly, no one has used such a combination in which the precise accurate timing circuitry of the watch is used to provide both timing for the signal processing and display of pulse information. The additional accuracy possible allows the display of instantaneous pulse rate on a pulse by pulse basis unrecognized in the prior art. Further, the prior art does not recognize that by the simultaneous display of average and instantaneous values of the wearer's pulse rate, the comparison between instantaneous and average pulse rate may be accomplished to give a direct indication of abnormalities, and the exact time of the abnormality occurrence may be observed.

BRIEF DESCRIPTION OF THE INVENTION

We have discovered that greatly enhanced utility for wrist-borne pulse rate meters is possible by combining the available technology in digital watches with improved signal processing to detect the actual instantaneous pulse rate of the wearer on a pulse by pulse basis, and to simultaneously calculate and display the average pulse rate over a period of time equal to "N" pulses. Thus employing our invention the wearer is able to simultaneously observe his average pulse rate and the last pulse rate. This allows the wearer to follow the cardiac response to changing work loads and to detect abnormalities in his pulse rate which otherwise would be submerged in averaging type circuitry. A simulta-

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neous display of average and instantaneous pulse rate may show a difference between the two which is of no significance, for example by movement of the sensor on the skin or other external interference. On the other hand the display of instantaneous rate may indicate the existence of premature ventricular contractions of the heart requiring the attention of the wearer's physician. The availability of actual time data allows the wearer to know when deviations occurred and this can be calibrated with the nature of his activity, the extent of exertion and physical location if later desired. In accordance with our invention there is the elimination of ambiguity present in many of the types of digital displays where the common field is used to display sequentially data of a different nature requiring the user to first ascertain what data is being displayed followed by an observation and analysis of the data. The data may have changed between the time that the first appraisal is made and the second observation, resulting in a confusing situation.

In accordance with this invention a device which has the general appearance of a digital watch is employed. On the outer face there are a pair of windows. One window displays real time in accordance with common practice for digital watches. The second window, having six digits for data presentation, allocates three spaces to average pulse value and three spaces to the instantaneous pulse value. Selector switches, one for the time record, and the other for the pulse display, are located in the edge of the watch case for easy access. They are of different shape and location to allow tactile identification.

The under face of the case includes a pulse transducer. In one embodiment the pulse transducer is an electro-mechanical device such as a piezoelectric crystal. When the transducer is an electro-mechanical device, the watch must be worn on the volar surface of the wrist but lateral to the tendon cord bundles. In the sub pollex depression, the pulse of the radial artery may be obtained. The ulnar pulse may be obtained on the opposite side of the tendon cord bundle from the radial artery.

In the preferred embodiment the pulse transducer is a light source such as an LED centrally located and encircled by a light detector such as a photo diode. A pair of light blocking rings integral with a lower case face isolate the photo detector from direct view from the light source and from view of the ambient light when the lower face is in contact with the wearer's body e.g. the wrist. In the employment of the light backscatter sensing described above, the watch is worn on the lateral surface of the wrist so that the sensors can respond to the pulse induced changes in the arteriolar and capillary beds in the subcutaneous tissues.

The circuitry accomplishing the improved results of this invention employs a common oscillator which is used to drive both the timing circuitry and display circuitry. The timing circuitry for the watch constitutes well known dividers, counters, a multiplexer and driving circuitry. The display similarly is one of the well known types of LED or liquid crystal. This display is commonly found in watches of the digital type.

The pulse signal processing circuitry of this invention is driven by the same oscillator used in the watch timing functions and includes a circuitry for developing a trigger signal for each pulse of the wearer and for converting the train of clock beats into a stored frequency

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count in pulses per minute. The last read pulse rate is stored and the values of the last "N" pulse rates are stored. The last pulse rate is displayed via the multiplexer and display. The average of the last "N" rates is determined via a divide by "N" circuit and is likewise displayed via the multiplexer and the display.

Where six digits of time information are desired for example, hour, minutes and seconds, six-digit display is used for time. Employing this invention six digits are required for a display of average and instantaneous pulse rates. Thus two identical six-digit displays are employed in this invention. The time functions are presented in a 3×2 digital display and the pulse rates are presented in a 2×3 digital display.

A novel infra-red source-detector combination is disclosed employing a concentric arrangement of light source and detector and light blocking bosses surrounding each.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a front face view of the combined digital watch and pulse rate meter of this invention with the straps shown in fragmentary form;

FIG. 2 is a rear view of the invention of FIG. 1;

FIG. 3 is a side elevational view thereof;

FIG. 4 is a rear face view of an alternate embodiment of this invention;

FIG. 5 is a side elevational view of the alternate embodiment of FIG. 4;

FIG. 6 is a fragmentary sectional view of the sensor portion of the embodiment of FIGS. 1 through 3 taken along line 6—6 of FIG. 2;

FIGS. 7 and 8 constitute a block diagram of the circuitry of this invention; and

FIG. 9 is a layout diagram for FIGS. 7 and 8.

DETAILED DESCRIPTION OF THE INVENTION

This invention is embodied in a combination wrist-watch pulse rate meter in the form best seen in FIG. 1. There, the combination of this invention generally designated 10 is all enclosed within a watch type case 11 having a front face region 12 with a pair of windows 13 and 14. Each of the windows 13 and 14 contain display means, for example, LED, liquid crystal, or other type of visual display commonly used in digital watches. In the preferred embodiment each have a six-digit display which may be similar for purposes of minimization of types of parts utilized in the manufacture. Since it is preferred that the time display has multiple selectable time displays—typical labeling under the time displays is as disclosed. The time functions preferred to be available on demand include:

Date—Day and hour

Hours, Minutes, Seconds and elapsed time

Minutes, Seconds, 0.01 seconds.

In the window 14 again a six-digit display is used but in this case the first three digits display the average pulse rate and the legend indicating the average is located on the front face 12 below the window 14, more particularly below the first three digits space, and the last three digits display the instantaneous pulse rate and is so identified by legend on the face 12. The use of two separate displays is advantageous in that it presents the actual time of the reading and less confusing readout, particularly for the jogger or one who is wearing this invention for medical reasons. Time always appears in one window and pulse rate in the other.

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In FIG. 1 the time is registered as 7 hours, 30 minutes and 0 seconds while a typical pulse rate for one engaged in athletic activity is displayed in the lower window 14. The instrument 10 registers an average rate of 122 pulses per minute with an instantaneous or last pulse at a rate of 119 pulses per minute.

In addition to the desirability of dual independent space for time and pulse information, simultaneous display of average pulse rates and instantaneous pulse rate is of significant importance. Prior art pulse rate meters using less precise circuitry employ averaging to avoid displaying an abnormality related to either patient movement relative to the transducer or errors in signal processing. In accordance with this invention, the simultaneous display of average and instantaneous pulse rate provides three important sets of information; the two values displayed plus the simultaneous comparison of the two. The average pulse rate is important in showing the trend over a number of cycles and will tend to change less dramatically. Thus a jogger can watch his pulse climb from start of activity towards the limit he or his doctor has set.

Any abnormality in any one pulse is clearly displayed in the right three digits of the pulse rate display. Its displacement from the average rate indicates the abnormality to the wearer at the same instant he is observing the average rate. The abnormality may indicate a premature ventricular contraction of the heart about which the wearer should be concerned based upon his doctor's evaluation, or it may be due to some abnormality of movement of the watch on the wrist or due to some abrupt change in the activity of the user.

Thus, the average value and the instantaneous value both bear significant information and the comparison of the two values made possible by this simultaneous display in the same window provides additional significant information to the wearer. The time display is simultaneously available. Thus, time of occurrence is observable as well.

The combination of this invention preferably includes three controls—15, 16, and 17 as follows:

Function			Positions
Watch	Switch 15	Date or time selection	Display off
			Date on
Pulse Rate	Switch 16	Pulse Sensor and Display Condition	Time on
			(1) Sensor and Display OFF
			(2) Sensor and Display ON
			(3) Sensor OFF Display locked
Timer or Stop Watch	Switch 17	Control Stop Watch Timer and Display	(1) Timer OFF/Reset
			Display OFF
			(2) Timer ON Display ON
			(3) Timer OFF Display Locked ON to fast recording.

The timer function is useful particularly for one doing timed exercises or jogging but is not mandatory. It employs the accurate timing circuitry of the watch and uses its display as well. To aid in eliminating any ambiguity in the nature of the reading, the timer switch 17 further produces the display of a decimal point ahead of the hundredths position. This signal plus the rapid change of the last two positions (hundredths of a sec-

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ond) gives the user a clear indication that the timer fraction is being displayed in the time window 13.

Switch 15 will have three fixed positions to select the time function display mode and pulse mode for setting or adjusting time functions.

The combination 10 is held on the wearer's body by a pair of straps 20 and 21 which may be ordinary watch straps in the preferred embodiment of this invention since all powering, sensing and control features of this invention are contained within the case 11.

Now referring to FIGS. 2-5, which are side and under side views of the invention of FIG. 1, the typical relationship of the straps 20 and 21 to the case 11 are more clearly apparent, and in these views the transducer portion on the underside of the case 11 may be seen. This transducer structure is contained within a boss region 22 of substantial diameter in order to provide a relatively large area of intimate contact with the user's wrist. This will insure both comfortable wearing and sufficient contact for obtaining an accurate pulse indication by either a pulse transducer of the pressure type contained therein shown in FIGS. 4 and 5, or by the preferred embodiment employing an infra-red source-detector combination as best shown in FIG. 2.

Watch straps must provide adjustable tension in as much as the sensors must be forced into the flesh of the wrist for a reading. This situation may be uncomfortable over a prolonged period of time and the strap may include provision for release of pressure during normal wearing.

A suitable detector is the type CLT 2160 photo diode produced by Clairex Electronics, Inc., of Mount Vernon, New York 10550.

Centrally located within the detector 23 is a secondary boss 22A, and an infra-red source 24 which may, for example, be a light emitting diode such as type SSL 55 CF of the General Electric Company, which provides emissions in the near infra-red region.

The circular detector array 23 surrounding the infra red source 24 insures a detection of the change in optical backscatter of the subcutaneous arteriolar and capillary bed of the wearer with each heart contraction and resultant pulse of oxygenated blood. The boss 22 serves to isolate the infra-red detector from ambient light. The boss 22A prevents direct transmission of light between source 24 and detectors 23. The coaxial arrangement of these three elements provides a relatively large contact surface area resulting in not only effective sensing of a pulse rate but minimum discomfort to the wearer. The circular array of the detector 23 allows the detection of pulses in a substantial arteriolar-capillary bed within the hemispherical region denoted in FIG. 6 for increased signal to noise ratio and energy utilization. In FIG. 3 in partial cross-section, two sections of a single circular apertured disc photo-detector, 23a, are shown. The single photo-detector 23a, or the circular array 23 of FIG. 2 allows integration of the backscatter field which serves the dual purpose of increasing signal sensitivity and reducing position dependence of the pulse meter.

An alternate, less preferred transducer is illustrated in FIGS. 4 and 5. There boss 32, similar to boss 22, is present however, a pressure transducer 33 constitutes the pulse source in direct contact with the wrist of the wearer. The transducer 32 may be of the piezoelectric or other type well known in the art.

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DESCRIPTION OF THE CIRCUITRY

The circuitry of this invention which provides for the combination of time, average pulse rate and instantaneous pulse rate information is represented in accordance with the preferred circuitry as shown in block diagram form in FIGS. 7 and 8.

Now referring to FIGS. 7 and 8 in conjunction with FIGS. 1 through 6 for reference, the basic timing element of this invention is an oscillator 100, for example a crystal oscillator operating at a suitable frequency, for example 2²¹ Hz. There are precision oscillator crystals mass produced for watch circuits with nominal frequencies of 2¹⁵ Hz and at 2¹⁶ Hz. The 2¹⁵ Hz is too slow for both precision timing and computation storage and is based upon every pulse period. The 2¹⁶ Hz is marginal. The 2²¹ Hz is also a mass produced, precision crystal which may be economically employed. At this frequency there is ample speed to execute all of the timing, storage, computational, transfer and display functions. The output of the oscillator 100 is introduced into the cascaded divider network 101 constituting a plurality of divider steps so arranged to provide sub-multiples of the basic frequency. Typical frequencies of the divider 101 used are 2¹⁰ Hz used to control the chronometric measurements, 2³ Hz used to control frequency steering logic and display logic; 2⁹ Hz for use in the pulse signal acquisition and processing circuit and 2²¹ Hz used in the processing storage and computing of pulse-rates.

The 2¹⁰ Hz signal from the divider 101 is itself introduced in two series connected converters or dividers 102 and 103; the former, converting the 2¹⁰ Hz signal to the train of pulses of one millisecond duration, and the divider 103 providing 0.01 second timing pulses which are used to drive a hundredth of a second counter 104. The 0.01 second counter 104 is in actuality two cascaded decade counters. Upon overflow after a count of 99 this counter 104 automatically resets to a count of 00.

The seconds counter 105 is actually two decade counters set to overflow and reset to 00 after reaching a count of 59. At each overflow and reset a pulse is sent to the minutes counter 106. Thus counter 104 produces an output pulse to a seconds counter 105 every 100 pulses constituting one second. The seconds counter 105 in turn produces one output pulse to a minutes counter 106 every sixty seconds. The second counter 105 is actually two decade counters set to overflow and reset to 00 after reaching a count of 59. At each overflow and reset, a pulse is sent to the minutes counter 106. The minutes counter in turn produces an output pulse each sixty counts to an hours counter 107. The hours counter 107 produces a single output pulse to a day counter 108 once each 24 hours. The day counter 108 in turn produces an output pulse for each pulse, and this latter pulse is introduced into the date counter 109 which in turn provides output pulses once each day to the multiplexer 112. The display elements must be presented at a rate faster than the normal human flicker perception which is approximately 16 Hz, or 2⁴ Hz. Digital displays at 64 Hz are perceived as a steady source. Strobe pulses for the multiplexer 112 are provided by a 2ⁿ Hz strobe and digit driver circuit 113 which is additionally connected to a strobe source for the display if required. The multiplexer 112 provides the output of the stored information introduced by each time function source from 1/100th seconds through the date counter to the segment decoder and segment

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driver circuit 114 which is directly connected to the date time display in windows 114 in FIG. 1. Each of the foregoing aspects of the chronometry circuitry is well known in the digital watch field and a more complete understanding of the selection and operation of such circuitry may be had by reference to a number of prior patents or publications but particularly the article entitled "An I²L Watch Chip with Direct LED Drive" article entitled ("An I² Watch Chip with Direct LED Drive") appearing in the Journal of Solid State Circuits, Vol. SC-11 No. 6, December 1976 at Page 847 et seq by Patrick A. Tucci and Louis K. Russell.

PULSE METER

The pulse measuring portions of this invention are all driven by the same basic oscillator 100 which drives the chronometric system. The basic timing frequency from the crystal oscillator 100 has been divided into sub-multiple frequencies 2⁹ Hz, 2¹¹ Hz, and 2²¹ Hz in the divider 101 and are used in the pulse signal portions of the invention.

Signal acquisition employing our preferred embodiment is accomplished in the block identified as 150, Signal Acquisition. It includes the infra-red signal source 24 which optionally, in order to save power, may be pulsed under the control of a pulse power source, 24A. Typically, a duty cycle of 20 percent is suitable at a pulse rate of 2 KHz.

The infra-red detector 23 will detect the backscatter signal emanating from the wrist of the body portion of the wearer in the form of a 2 KHz signal modulated in amplitude at the pulse rate of the individual. This signal is then passed through a suitable amplifier having gain, for example of 1000, and through a band pass filter BPF typically having a pass band of 1000 Hz centered at 2 KHz. The signal is then envelope detected in a suitable detector to provide the pulse wave and filtered through a low pass filter having a cutoff in the order of 10 Hz to eliminate such interference as 60 cycle hum or other higher frequency signals that might be picked up. The detected filtered pulse signal is then introduced into signal conversion circuit 152 which typically includes a pulse square and inverter to provide an output square wave at the frequency of the wearer's pulse. This signal is then introduced as the switching signal to a bi-stable multivibrator 153 having a pair of AND gates, each having one input coupled to output leads of opposite states of the multivibrator 153. The second input to each AND gate is a timing signal at a 2⁹ Hz frequency. Each of these AND gates will pass the 2⁹ Hz signals to their respective counter 154 and 155 for the period that the multivibrator 153 is in an ON state associated with that particular AND gate. The counter 154 termed the Nth period counter, stores the number of 2⁹ Hz pulses which pass through its associated AND gate. Similarly, the counter 155 which is identified as Nth+1 period counter, stores the number of 2^N Hz pulses passing through its associated AND gate when enabled. When there is no change in the pulse rate between two successive individual pulses of the wearer, the count in both counters 154 and 155 will be identical. As the pulse rate of the wearer changes, the count in the counters 154 and 155 will each change accordingly. The change from pulse rate from counter period to counter period reflects the wearer's change in pulse rate on a per pulse basis.

Both the counters 154 and 155 are under the control of a counter transfer and reset logic circuit 156, which

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is itself under the control of flip-flop 153. As each counter is loaded via its respective AND gate and the flip-flop switches to the opposite state, a dump signal is received from the transferred logic circuit 156 followed by reset applied to that particular counter. The count in each counter is sequentially introduced into the last period counter register-157, itself controlled by the logic circuit 156. The count in register 157 is introduced into a divider 159 immediately before reloading. In the divider 159, the count present in the register 157 is divided into the constant 60×2^9 from counter 168. The output of the divider 159 is the rate in pulses per minute. It is introduced into counter register 160 and in turn introduced into last pulse rate register 161 where the last pulse rate in pulse per minute is temporarily stored. Output lead 171 from the register 161 is used to convey that last pulse rate signal to multiplexer 112 where it is in turn applied to the instantaneous pulse display. In addition to the register 161, there are four storage registers 163 through 166, each of which store the last four sequential pulse rates with the transfer of pulse rates between the stages 161 through 166 under the control of shift logic circuit 162. The total number of pulses in the registers 163 through 166 is obtained in adder 167. By dividing by 2² in divider 168, the number of storage registers 163 through 167, the average pulse rate for the last four pulses is obtained and introduced via lead 172 after passing through an average count register 169. The running average on lead 172 is also introduced into the multiplexer 112 for display in the average pulse position digits of display 14 of FIG. 1.

What is claimed is:

1. A combined digital watch and pulse rate meter comprising:

- a case having an upper face and a lower face;
- the upper face including display means for display in digital form time of any information;
- said display further including means for displaying the six digits of pulse information;
- a timing signal generator within said case;
- timing circuitry coupled to said timing signal generator for deriving fractions of seconds, seconds and minutes information;
- means for displaying said time information on said display;
- a transducer on the inner face of said case positionable in pulse sensing relationship with the wearer;
- said transducer coupled to signal processing circuitry for deriving the pulse rate of the wearer;
- said signal processing circuitry coupled to said timing signal generator to provide a time base for pulse measurement accuracy equal to the accuracy of the time of day signal;
- means for coupling pulse information from said signal processing circuitry to three digits of said display on a pulse by pulse basis to provide instantaneous pulse rate display;
- means for storing the last "N" pulse rates detected;
- means for averaging the last "N" pulse rates stored;
- and
- means for coupling the average pulse rate to the last set of three digits of said display whereby the pulse rate average is displayed for the wearer.

2. The combination in accordance with claim 1 wherein said display means comprise a pair of six digit decimal displays whereby time and pulse information may be simultaneously displayed for continuous comparison by the wearer.

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3. The combination in accordance with claim 2 wherein said pulse rate display is controlled and enabled by a single switch means whereby average and instantaneous pulse rate values are simultaneously displayed.

4. The combination in accordance with claim 1 wherein "N" is four.

5. A combined digital watch and pulse rate meter comprising:

- a case having an upper and a lower face;
- the upper face including digital display means for displaying time information;
- said display means including means for displaying six digits of pulse information;
- a timing signal generator within said case;
- timing circuitry coupled to said timing signal generator for deriving fraction of seconds, seconds and minutes information;
- means for displaying said time information on said display;
- a transducer on the inner face of said case positionable in pulse sensing relationship with the wearer;
- said transducer coupled to signal processing circuitry for deriving the pulse rate of the wearer;
- said signal processing circuitry coupled to said timing signal generator to provide a time base for pulse measurement accuracy equal to the accuracy of the time signal;
- means for coupling pulse information from said signal processing circuitry to three digits of said display on a pulse by pulse basis to provide instantaneous pulse rate display;
- means for storing the last "N" pulse rates detected;
- means for averaging the last "N" pulse rates stored;
- means for coupling the average pulse rate to the last set of three digits of said display whereby the pulse rate average is displayed for the wearer;
- wherein said signal transducer comprises a light source having a frequency distribution including the 900 nanometer range positioned at a central location in the rear face of the case;
- photodetector means positioned radially around said light emitting source;
- first light obstructing means preventing direct illumination of said photo detector means by said light source;
- second light obstructing means shielding said photo detector means from external sources when the lower face of said case is maintained in contact with the skin of the wearer;
- wherein said first and second light obstructing means comprise a pair of annular rings extending above the surface of the lower face of said case whereby said rings are in contact with the skin of the wearer and light transmission to said detector is limited to light emanating from the skin of the wearer.

6. The combination in accordance with claim 5 wherein said light detector comprises a continuous ring detector located between the first and second light obstructing rings.

7. The combination in accordance with claim 6 wherein said light source comprises a light emitting diode.

8. The combination in accordance with claim 6 wherein said light detector comprises a photo diode.

9. A pulse rate meter to be worn by a user comprising:

- A case;

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means holding one side of said case against the wearers body;

- said case enclosing
- (a) a timing signal source;
- (b) a sensor in pulse sensing relationship with the wearer for producing an electrical signal for each pulse of the user;
- (c) means for converting the pulse rate of the user into a train of timing signals, the number of which define the pulse period for each pulse period of the user;
- (d) two counting means;
- (e) means coupling trains of timing signals in alternate sequential order to said two counting means;
- (f) a register;
- (g) control means for alternately introducing the count of said two counting means into said register and for resetting said counting means;
- (h) means for converting the count from said register into the wearer's pulse rate;
- (i) a display means on an outer wall of said case;
- (j) means for applying the output of said converting means to said display to display the user's pulse rate for the last pulse;
- (k) means for storing "N" signals representative of "N" pulse rates measured;
- (l) means for averaging said "N" pulse rates measured; and
- (m) means for applying the output of said averaging means to said display means whereby both the instantaneous and average pulse rates are available to the user by observation of the display on said case wall.

10. The combination in accordance with claim 9 wherein said display includes sufficient digits to display both average and instantaneous pulse rates simultaneously and said instantaneous and average pulse rates are applied simultaneously thereto.

11. The combination in accordance with claim 9 wherein said number "N" is four.

12. The combination in accordance with claim 9 including "N" storage registers coupled to said converting means in service whereby each of the last "N" pulse rates is stored in sequence, said averaging means operative to average the last "N" pulse rates and whereby a running average of "N" pulse rates is displayed.

13. The combination in accordance with claim 9 including clock means for timing seconds, minutes and hours;

- said display means coupled to said clock means including means for displaying seconds, minutes and hours as determined by said clock means;
- said pulse meter and clock means both employing said timing signal source.

14. The combination in accordance with claim 9 including an elapsed time measuring circuit;

- said display means coupled to said elapsed time measuring circuit;
- said pulse meter and elapsed time measuring circuit both employing said timing signal source.

15. An improved pulse rate meter comprising:

- a housing including an upper face and a lower face;
- display means on said upper face for displaying pulse rate information;
- sensor means on said lower face for sensing the wearer's pulse rate;
- means securing said housing to the wearer with the lower face in contact with the wearer's skin;

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said sensor means comprising a source of radiant energy;
at least one radiant energy detector laterally displaced on said lower face of said housing from said source of radiant energy;
means on said lower face for blocking direct radiation from said source of radiant energy to said detector;
second means on said lower means for blocking radi-

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ant energy to said detector from said radiant energy source except that reradiating from the skin of the wearer;
wherein said first and second radiant energy blocking means comprises a pair of concentric raised bosses on the lower face of said housing.

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**APPX 70518-70559
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APPX 70504-70513
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APPX70592-70594
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APPX70610-70613
ENTIRELY REDACTED

APPX70615-70617
ENTIRELY REDACTED

APPX70619-70628
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Medical Monitoring Pioneer Announces the Limited Market Release of the Masimo W1... Page 1 of 6



**Medical Monitoring Pioneer Announces the Limited
Market Release of the Masimo W1™ Watch for
Consumers**

*On Its Anniversary, the Inventor of Measure-through Motion and Low
Perfusion™ Pulse Oximetry Introduces the First Health Watch to Offer
Accurate, Continuous Measurements*



Masimo W1™ (Photo: Business Wire)

May 02, 2022 08:00 AM Eastern Daylight Time

IRVINE, Calif.--(BUSINESS WIRE)--Masimo (NASDAQ: MASI) marks its 33rd anniversary today by announcing the limited market release of the W1™ health watch for consumers. The first of its kind, the Masimo W1 offers accurate, continuous measurements and actionable health insights – from the leader in hospital pulse oximetry – in a personal, discreet, lifestyle-friendly wrist-worn wearable. Building on Masimo’s decades of leadership in creating revolutionary noninvasive blood parameter monitoring solutions, W1 provides accurate, continuous monitoring of multiple health parameters – including oxygen saturation (SpO₂), pulse rate, perfusion index, PVi®, and respiration rate, alongside step count and fall detection.

Incorporated on May 2, 1989 as a garage startup dedicated to solving the “unsolvable” problem of inaccurate and unreliable conventional pulse oximetry under real-life conditions such as patient movement, Masimo and its breakthrough Measure-through Motion and Low Perfusion™ SET® pulse oximetry today touch hundreds of millions of lives around the world each year.¹ SET® pulse oximetry has been shown in more than 100 independent studies to outperform other pulse oximetry technologies,² and is the only pulse oximetry shown in numerous large studies – involving more than 300,000 infants – to improve critical congenital heart disease (CCHD) screening in newborns.³⁻¹³ SET® pulse oximetry has also been shown to improve outcomes for patients on opioids in post-surgical wards,¹⁴⁻¹⁷ reduce eye damage and blindness in the neonatal intensive care unit,¹⁸ and reduce

mortality among Covid patients remotely monitored at home.¹⁹ Through Masimo's continued focus on innovation and improvement, SET® has evolved to feature the industry's highest accuracy specifications, on the new RD line of patient sensors; become tetherless, with the secure Bluetooth®-equipped continuous Radius PPG™; and now, as the foundational technology driving the W1, has become a truly lifestyle-friendly technology for consumers outside hospitals.

For the limited market release of W1, Masimo is inviting a select group of early adopters to help evaluate and refine the product over the coming months. Masimo will provide up to 10,000 W1s on a first-come, first-served basis, at a 50% discount, to users who agree to the program details and to provide feedback and data to Masimo. For additional information and to express interest in the program, please go to www.masimo.com/w1.

With this consumer release of W1, Masimo is bringing its expertise in medical monitoring, connectivity, and automation to consumers looking to take control of their personal health, including those wanting to fine-tune their athletic training and recovery, the quality of their sleep, and their overall physiological status. Paired via secure Bluetooth® to the Masimo Personal Health smartphone app, W1 provides continuous health data and guidance with accuracy heretofore unknown in a wrist-based device, unlocking meaningful, actionable insights—all in the convenient and discreet form of a durable watch.

Tommy Haas, former professional tennis player, commented, "I've always believed in the power of data to improve my performance. Accurate vital sign measurements have helped me track my activity and recovery both on and off the court. Now with Masimo W1, I have a convenient way to continuously track my vitals right on my wrist."

In addition to use by consumers, W1 is also available outside the U.S. for telehealth applications, benefiting from Masimo's expertise not only in noninvasive monitoring but in hospital connectivity and automation innovations. For patients recovering at home after surgery or illness, as well as patients with chronic conditions (such as heart failure, COPD, or cancer), W1 represents a convenient, reliable remote patient monitoring and telehealth solution enabling clinicians to keep track of their patients' physiological status from afar, even as patients go about everyday tasks at home. A natural complement to the Masimo SafetyNet® remote patient monitoring platform, W1 enables wireless transmission of patient data to the Masimo SafetyNet smartphone app and Masimo's secure data cloud.

Dr. Abeer Bakhsh, Head of the Heart Function Unit at Prince Sultan Cardiac Center in Saudi Arabia, which has been using W1 for telehealth monitoring of patients, commented, "We have begun using Masimo W1 with Masimo SafetyNet for remote patient monitoring of our chronic heart failure patients. The watch is very comfortable to wear, and the continuous Masimo measurements give us confidence to help keep our patients safe."

Joe Kiani, Founder and CEO of Masimo, said, "As we celebrate our 33rd year, and as we embark on the next chapter of our expansion through the recent acquisition of Bowers & Wilkins, Denon, Marantz, Polk Audio and their home automation technologies, it is only fitting that we are today debuting the first wearable device to offer accurate and continuous physiological measurements based on the technology we've honed for use in hospitals for more than three decades. From our own original breakthrough technology, SET® pulse oximetry, to our advanced hospital monitors like Root®, to our Hospital Automation™ platform and its many innovative connectivity and remote monitoring systems, to our tetherless Masimo SafetyNet remote and home patient management and telehealth solutions, and now to W1, we are excited to be able to bring our technologies directly to even more people everywhere."

The Masimo W1 is not FDA cleared.

[@Masimo](#) | [#Masimo](#)

About Masimo

Masimo (NASDAQ: MASI) is a global medical technology company that develops and produces a wide array of industry-leading monitoring technologies, including innovative measurements, sensors, patient monitors, and automation and connectivity solutions. Our mission is to improve patient outcomes and reduce the cost of care. Masimo SET[®] Measure-through Motion and Low Perfusion[™] pulse oximetry, introduced in 1995, has been shown in over 100 independent and objective studies to outperform other pulse oximetry technologies.² Masimo SET[®] has also been shown to help clinicians reduce severe retinopathy of prematurity in neonates,¹⁸ improve CCHD screening in newborns,⁴⁻¹³ and, when used for continuous monitoring with Masimo Patient SafetyNet[™] in post-surgical wards, reduce rapid response team activations, ICU transfers, and costs.¹⁴⁻¹⁷ Masimo SET[®] is estimated to be used on more than 200 million patients in leading hospitals and other healthcare settings around the world,¹ and is the primary pulse oximetry at 9 of the top 10 hospitals as ranked in the 2021-22 *U.S. News and World Report* Best Hospitals Honor Roll.²⁰ Masimo continues to refine SET[®] and in 2018, announced that SpO₂ accuracy on RD SET[®] sensors during conditions of motion has been significantly improved, providing clinicians with even greater confidence that the SpO₂ values they rely on accurately reflect a patient's physiological status. In 2005, Masimo introduced rainbow[®] Pulse CO-Oximetry technology, allowing noninvasive and continuous monitoring of blood constituents that previously could only be measured invasively, including total hemoglobin (SpHb[®]), oxygen content (SpOC[™]), carboxyhemoglobin (SpCO[®]), methemoglobin (SpMet[®]), Pleth Variability Index (PVi[®]), RPPVi[™] (rainbow[®] PVi), and Oxygen Reserve Index (ORi[™]). In 2013, Masimo introduced the Root[®] Patient Monitoring and Connectivity Platform, built from the ground up to be as flexible and expandable as possible to facilitate the addition of other Masimo and third-party monitoring technologies; key Masimo additions include Next Generation SedLine[®] Brain Function Monitoring, O3[®] Regional Oximetry, and ISA[™] Capnography with NomoLine[®] sampling lines. Masimo's family of continuous and spot-check monitoring Pulse CO-Oximeters[®] includes devices designed for use in a variety of clinical and non-clinical scenarios, including tetherless, wearable technology, such as Radius-7[®] and Radius PPG[™], portable devices like Rad-67[®], fingertip pulse oximeters like MightySat[®] Rx, and devices available for use both in the hospital and at home, such as Rad-97[®]. Masimo hospital automation and connectivity solutions are centered around the Masimo Hospital Automation[™] platform, and include Iris[®] Gateway, iSirona[™], Patient SafetyNet, Replica[®], Halo ION[™], UniView[®], UniView :60[™], and Masimo SafetyNet[®]. In 2022, Masimo acquired Sound United, a leading developer of premium consumer sound and home integration technologies. Additional information about Masimo and its products may be found at www.masimo.com. Published clinical studies on Masimo products can be found at www.masimo.com/evidence/featured-studies/feature/.

ORi and RPPVi have not received FDA 510(k) clearance and are not available for sale in the United States. The use of the trademark Patient SafetyNet is under license from University HealthSystem Consortium.

References

1. Estimate: Masimo data on file.
2. Published clinical studies on pulse oximetry and the benefits of Masimo SET[®] can be found on our website at <http://www.masimo.com>.

Comparative studies include independent and objective studies which are comprised of abstracts presented at scientific meetings and peer-reviewed journal articles.

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Forward-Looking Statements

This press release includes forward-looking statements as defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, in connection with the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, among others, statements regarding the potential effectiveness of Masimo W1™. These forward-looking statements are based on current expectations about future events affecting us and are subject to risks and uncertainties, all of which are difficult to predict and many of which are beyond our control and could cause our actual results to differ materially and adversely from those expressed in our forward-looking statements as a result of various risk factors, including, but not limited to: risks related to our assumptions regarding the repeatability of clinical results; risks related to our belief that Masimo's unique technologies, including W1, contribute to positive clinical outcomes and patient safety; risks that Masimo W1 fails to be available as planned; risks related to our belief that Masimo noninvasive medical breakthroughs provide cost-effective solutions and unique advantages; risks related to COVID-19; as well as other factors discussed in the "Risk Factors" section of our most recent reports filed with the Securities and Exchange Commission ("SEC"), which may be obtained for free at the SEC's website at www.sec.gov. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. All forward-looking statements included in this press release are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today's date. We do not undertake any obligation to update, amend or clarify these statements or the "Risk Factors" contained in our most recent reports filed with the SEC, whether as a result of new information, future events or otherwise, except as may be required under the applicable securities laws.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/019,448	03/13/2024	10912502	50095-0043RX1	4766
64735	7590	05/30/2024		
Knobbe, Martens, Olson & Bear, LLP MASIMO CORPORATION (MASIMO) 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER REICHLE, KARIN M	
			ART UNIT	PAPER NUMBER
			3992	
			MAIL DATE	DELIVERY MODE
			05/30/2024	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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***EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM**

REEXAMINATION CONTROL NO. 90/019,448 .

PATENT UNDER REEXAMINATION 10912502 .

ART UNIT 3992 .

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Denying Request For Ex Parte Reexamination	Control No. 90/019,448	Patent Under Reexamination 10912502	
	Examiner Karin M Reichle	Art Unit 3992	AIA (FITF) Status No

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed 03/13/2024 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) ☐ PTO-892, b) ☒ PTO/SB/08, c) ☐ Other: _____

The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

- a) ☐ by Treasury check or,
- b) ☒ by credit to Deposit Account No. 06-1050 , or
- c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C.303(c)).

/Karin Reichle/
Primary Examiner, Art Unit 3992

cc: Requester (if third party requester)

Application/Control Number: 90/019,448
Art Unit: 3992

Page 2

DECISION ON REQUEST FOR *EX PARTE* REEXAMINATION

Third Party Requester (TPR) submitted a request for reexamination of claims 19-22 and 28 of US Patent No. 10,912,502 (hereinafter also referred to as ‘502 or Poeze ‘502) on March 13, 2024. **No** substantial new question of patentability affecting claims 19-22 and 28 of United States Patent Number 10,912,502 is raised by the request for *ex parte* reexamination and prior art cited therein for the reasons set forth below.

Summary of Prosecution History

17/031,407 Prosecution (Exhibit 1002)

The ‘502 patent was filed as application 17/031,407 (hereinafter also referred to as ‘407) on September 24, 2020. The ‘768 Patent was originally filed with original independent claim 1.

On December 22, 2020, three IDS were filed. Among the references cited were U.S. Patent App. Pub. No. 2002/0188210 to **Aizawa** et al. (“Aizawa”), U.S. Patent No. 4,880,304 to **Jaeb** et al. (“Jaeb”), U.S. Patent No. 7,764,982 (U.S. Patent App. Pub. No. 2006/0211924) to **Dalke** et al. (“Dalke”), U.S. Patent No. 8,233,955 (U.S. Patent App. Pub. No. 2007/0123763) to **Al-Ali** et al. (Al-Ali’), U.S. Patent App. Pub. No. 2005/0234317 to **Kiani** (“Kiani”), US Pub. No. 2007/0093786 to **Goldsmith** et al (“Goldsmith”) and U.S. Patent No. 7,558,622 (U.S. Patent App. Pub. No. 2008/0001735) to **Tran** (“Tran”).

On October 26, 2020, a preliminary amendment was filed which cancelled claim 1 and added claims 2-31.

On November 19, 2020, six more IDS were filed. Among the references cited were U.S. Patent No. 5,817,008 to **Rafert** et al. (“Rafert”) and US. Patent No. 6,356,774 to **Bernstein** et al. (“Bernstein”). A Terminal disclaimer was also filed.

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Art Unit: 3992

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On November 24, 2 further IDS were filed. On November 30, another IDS was filed.

On December 3, an Interview Summary issued summarizing an interview held November 30, 2020 in which proposed amendments to claims 2, 20 and 30 were discussed.

On December 1, another preliminary amendment was filed. Claims 2, 6, 12, 20, 24, and 30 were amended and claim 23 was cancelled. Claim 32 was added.

A Notice of Allowance (NOA) issued on December 9, 2020. Claims 2-22 and 24-32 were allowed and renumbered 1-30 respectively. The examiner's statement of reasons for allowance explicitly discussed U.S. Patent Nos. 4,129,124 ("Thalmann"), 4,880,304 ("**Jaeb**"), 5,893,364 ("Haar"), and 8,352,003 ("Sawada"). The examiner's statement of reasons for allowance further set forth:

However, the prior art of record does not teach or suggest "four photodiodes arranged on an interior surface of the user-worn device and configured to receive light after attenuation by tissue of the user; a protrusion comprising; a convex surface extending over the interior surface, a plurality of openings in the convex surface extending through the protrusion and aligned with the four photodiodes, each opening defined by an opaque surface, and a plurality of windows, each of the windows extending across a different one of the openings"; [see '502, claim 1] "four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user; a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material [sic] each opening positioned over a different one [sic] of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue; optically transparent material within each of the openings"; [see '502, claim 19] and "four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user; a thermistor configured to provide a temperature signal; a protrusion arranged above the interior surface, the protrusion comprising; [sic] a convex surface; a plurality of openings in the convex surface, extending through the protrusion [sic] and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping; and a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings; at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are

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Art Unit: 3992

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arranged on the interior surface within the cavities”, [see ‘502, claim 28] in combination with the other claimed elements/ steps.

U.S. Patent No. 10,912,502 issued on February 9, 2021.

Prior IPR Proceedings

Third Party Requester also filed a petition requesting *inter partes* review of claims 1-30 of ‘502 on July 15, 2022, IPR2022-01273. The petition asserted the following grounds of unpatentability

Claims Challenged	35 USC §	References/Basis
1-3, 5-9, 11-19, 25-27	103	Mendelson-799, Aizawa, Ohsaki, Scharf, and Dalke
4, 10, 20-24, 28-30	103	Mendelson-799, Aizawa, Ohsaki, Scharf, Dalke and Goldsmith
1-3, 5-9, 11-19, 25-27	103	Mendelson-799, Aizawa, Kotanagi, Scharf, and Dalke
4, 10, 20-24, 28-30	103	Mendelson-799, Aizawa, Kotanagi, Scharf, Dalke and Goldsmith

PTAB denied institution of the *inter partes* review ‘01273 on January 24, 2023.

Specifically, the PTAB determined “A principal feature of each of the independent claims of the ‘502 patent lies in the structure and arrangement of a “protrusion” located over four photodiodes arranged on an interior surface of a user-worn device...the protrusion feature requires a convex surface and multiple openings defined by an opaque surface and associated with a plurality of windows, with each window extending over a different opening. Independent claims 19 and 28 have similar requirements.” (‘01273 Decision, p. 15)

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The PTAB further determined “[w]ithout the guidance provided by the claims of the ’502 patent, it is difficult to conclude that Petitioner’s postulation as to a particular structure that results from combining the teachings of Mendelson-799, Aizawa, Ohsaki, and Scharf is based on an objective assessment of what those teachings would have conveyed to a skilled artisan. It is clear from the Petition, however, that such structural configuration is necessary as the basis for Petitioner’s approach to arriving at the structural requirements of the claims. At the outset, we share Patent Owner’s view and that of its declarant, Dr. Duckworth (Ex. 2002), that none of the prior art on which Petitioner relies discloses a convex protrusion with multiple openings for multiple detectors.” (’01273 Decision, pp. 18-19.)

Finally, the PTAB determined with regard to the combined teachings of Mendelson-799, Aizawa, Kotanagi, and Scharf and Kotanagi’s teachings for “the same reasons’ as was proposed for the grounds including Ohsaki and that Kotanagi provides ‘additional/alternative motivation’ to apply a convex protrusion in conjunction with the combined teachings of Mendelson-799 and Aizawa”, “[i]n our view, Petitioner’s proposed grounds of unpatentability for the challenged claims fare no better based on Kotanagi’s teachings than they did for those grounds based on Ohsaki’s teachings. For the same reasons discussed above, we conclude that Petitioner has not shown a reasonable likelihood of success in connection with any of its proposed grounds that involve the combined teachings of Mendelson-799, Aizawa, Kotanagi, and Scharf.” (’01273 Decision, p. 22.)

Requester also filed another petition requesting *inter partes* review of claims 1-30 of ’502 on July 15, 2022, IPR2022-01274. The petition asserted the following grounds of unpatentability:

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Claims Challenged	35 USC §	References/Basis
1-3, 5-7, 9, 11-18	103	Lumidigm, Scharf, and Kotanagi
4, 8, 10, 19-27, 28-30	103	Lumidigm, Scharf, Kotanagi and Tran

PTAB denied institution of the *inter partes* review ‘01274 on January 24, 2023.

Specifically, the PTAB determined “...in claim 1, the protrusion feature requires a convex surface and multiple openings defined by an opaque surface and associated with a plurality of windows, with each window extending over a different opening. Independent claims 19 and 28 have similar requirements.” (‘01274 Decision, p. 13)

The PTAB further determined “[w]ithout the guidance provided by the claims of the ’502 patent, it is difficult to conclude that Petitioner’s postulation as to a particular structure that results from combining the teachings of Lumidigm, Kotanagi and Scharf is based on an objective assessment of what those teachings would have conveyed to a skilled artisan. It is clear from the Petition, however, that such structural configuration is necessary as the basis for Petitioner’s approach to arriving at the structural requirements of the claims. At the outset, we share Patent Owner’s view and that of its declarant, Dr. Duckworth (Ex. 2002), that none of the prior art on which Petitioner relies discloses a convex protrusion with multiple openings for multiple detectors.” (‘01274 Decision, p. 16.)

Finally, the PTAB set forth “[a]s discussed above, Petitioner attempts to arrive at such structure through a proposed amalgamation of prior art teachings that must include, for instance, arranging a convex protrusion with multiple openings or separate glass windows over

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Lumidigm's optical sensors. In our view, however, Petitioner simply does not explain adequately why such configuration results from the actual teachings of the prior art. Moreover, in an effort to next account for a convex shape of the protrusions and openings, Petitioner relies on Kotanagi's curved protrusion. Although Petitioner, in a footnote, generally contends that 'other examples' of composite figure configurations "could be conceived" so as to render the challenged claims obvious, Petitioner does not provide further assessment or explanation in that regard. ... We find that general contention inadequately supported. as providing, for instance, "better contact" and be "more comfortable" for a user of Lumidigm's detector. ... Yet, consistent with the arguments advanced by Patent Owner and Dr. Duckworth, we are not satisfied that Petitioner adequately explains why a skilled artisan would have expected that such benefits would apply to the convoluted combination of modifications Petitioner proposes to arrive at the claimed invention. ... Nor has Petitioner explained adequately why a skilled artisan would have assessed that Petitioner's reasoning applies to a protrusion configured to have specific characteristics, e.g., multiple distinct openings and opaque lateral surfaces, intended to provide a particular function, i.e., reduction of light piping, that is unaffiliated with concerns of contact or comfort." ('01274 Decision, pp. 16-17)

Prior ITC Proceedings-377-TA-1276

In response to a complaint filed by Patent Owner alleging infringement of certain claims of the various of its patents, including the '502 patent, by Third Party Requester, an investigation was instituted on August 18, 2021. Prior to issuance of the Final ID, Patent Owner withdrew the allegation of infringement with respect to some of the claims such that at the time of the June

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2022 hearing only certain claims remained at issue including claims 22 and 28 of the ‘502 patent. (Exhibit 1027, pages 2-3.)

On January 10, 2023, the Final ID found Third Party Requester in violation as to only claims to another patent. On January 23, 2023 both parties filed petitions for review of the Final ID. On May 23, 2023 the Commission determined to review the Final ID in part including written description with regard to claim 28 of ‘502 and obviousness with regard to ‘502, i.e. whether claims 22 (which depends from claim 19) and 28 were invalid as obvious over combinations of references based on Lumidigm. (Exhibit 1027, pp. 6, 8-10, 16.)

On November 14, 2023 an Opinion was issued. On pages 48-49, of the Opinion concluded:

Regarding claim 28 of the ‘502 patent, Apple has not shown that this claim would have been prima facie obvious to a person of ordinary skill in the art. For example, Apple has failed to show that the prior art teaches or suggests elements [28PRE], [28G], [28I], [28J], and [28K].¹ Also, Complainants’ evidence of secondary considerations has minimal weight. In view of these underlying findings, the Commission concludes that Apple has not shown that this claim would have been invalid by clear and convincing evidence.

Regarding claim 22 of the ‘502 patent, Apple has not shown that this claim would have been prima facie obvious to a person of ordinary skill in the art. Apple has failed to show that the prior art teaches or suggests elements [19PRE], [19D], and [19E].² Also, Complainants’ evidence of secondary considerations has minimal weight. In view of these underlying findings, the Commission concludes that Apple has not shown that this claim would have been invalid by clear and convincing evidence.

¹ The features of a user-worn device configured to non-invasively measure an oxygen saturation of a user, a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings; one or more processors configured to receive one or more signals from at least one of the four photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal; a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network; and a user interface comprising a touch- screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user.

² The features of a user-worn device configured to non-invasively measure an oxygen saturation of a user, optically transparent material within each of the openings; and one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user.

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References Asserted as Raising a Substantial New Question (SNQ)

The assertions regarding claims 19-22 and 28 of the '502 patent are based upon the following references:

- 1) U.S. Patent Application No. 2002/0188210 to **Aizawa** et al. (hereinafter also referred to as Aizawa or '210 (Exhibit 1004)) filed May 23, 2002 and published December 12, 2002.
- 2) U.S. Patent No. 7,468,036 to **Rulkov** et al. (hereinafter also referred to as Rulkov or '036 (Exhibit 1005)) filed June 13, 2007 and issued December 23, 2008.
- 3) Japanese Patent Application JP2003-201849A to **Numaga** et al. (hereinafter also referred to as Numaga or '849 (Exhibit 1007-Translation Exhibit 1006)) filed July 25, 2003 and published February 17, 2005.
- 4) U.S. Patent No. 4,880,304 to **Jaeb** et al. (hereinafter also referred to as Jaeb or '304 (Exhibit 1008)) filed April 1, 1987 and issued November 14, 1989.
- 5) U.S. Patent Application No. 2006/0211924 to **Dalke** et al. (hereinafter also referred to as Dalke or '924 (Exhibit 1009)) filed March 1, 2006 and published September 21, 2006.
- 6) U.S. Patent App. Pub. No. 2007/0123763 to **Al-Ali** et al. (hereinafter also referred to as Al-Ali or '763 (Exhibit 1010)) filed November 29, 2006 and published May 31, 2007.
- 7) U.S. Patent App. Pub. No. 2006/0253007 to **Cheng** et al. (hereinafter also referred to as Cheng or '007 (Exhibit 1011)) filed November 1, 2005 and published November 9, 2006. ("Cheng")
- 8) U.S. Patent App. Pub. No. 2008/0316488 to **Mao** et al. (hereinafter also referred to as Mao or '488 (Exhibit 1012)) filed May 6, 2008 and published December 25, 2008.
- 9) U.S. Patent No. 5,817,008 to **Rafert** et al. (hereinafter also referred to as Rafert or '008 (Exhibit 1014)) filed October 31, 1996 and published October 6, 1998.
- 10) U.S. Patent App. Pub. No. 2005/0234317 to **Kiani** (hereinafter also referred to as Kiani or '317 (Exhibit 1028)) filed March 21, 2005 and published October 20, 2005.
- 11) U.S. Patent No. 6,356,774 to **Bernstein** et al. (hereinafter also referred to as Bernstein or '774 (Exhibit 1029)) filed September 28, 1999 and published March 12, 2002.
- 12) U.S. Patent No. 5,188,108 to **Secker** (hereinafter also referred to as Secker or '108 (Exhibit 1030)) filed January 23, 1991 and published February 23, 1993.
- 13) U.S. Patent App. Pub. No. 2008/0001735 to **Tran** (hereinafter also referred to as Tran or '735 (Exhibit 10334)) filed June 30, 2006 and published January 3, 2008.

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14) U.S. Patent Application No. 2007/0093786 to **Goldsmith** et al (hereinafter also referred to as Goldsmith or ‘786 (Exhibit 1037)) filed July 31, 2006 and published April 26, 2007.

Other

The Declaration of Dr. Brian W. Anthony (Exhibit 1003), executed March 7, and filed March 13, 2024. Pages 5-9 of the Declaration lists 38 “prior art references and materials” cited³ in the declaration in addition to the references asserted above.

All of the references, declaration and accompanying exhibits/attachments identified above and the Request have been reviewed and considered.

Availability of Asserted References as Prior Art

As an initial matter, see the cover page of the ‘502 patent, the ‘407 patent application was filed on September 24, 2020 but also claimed benefit to the filing dates of Provisional Applications, the earliest of which is July 3, 2008.

Reference (1) to **Aizawa** was filed on May 23, 2002, and was published on December 12, 2002, i.e. more than a year prior to the earliest claimed effective filing date of ‘502, i.e. July 3, 2008 and thus, is available as prior art under 35 USC 102(b) and 35 USC 103.

Reference (2) to **Rulkov** was filed on June 13, 2007, but issued on December 23, 2008, after the earliest claimed effective filing date of ‘502, i.e. July 3, 2008, and thus, is available as prior art under 35 USC 102(e) and 35 USC 103.

³ These “prior art references and materials”, though not asserted as raising an SNQ, are also discussed in the Request, see, e.g. pages 19-22.

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Reference (3) **Numaga** was filed on July 25, 2003, and published on February 17, 2005, i.e. more than a year prior to the earliest claimed effective filing date of '502, i.e. July 3, 2008 and thus, is available as prior art under 35 USC 102 (a), 102(b) and 35 USC 103.

Reference (4) to **Jaeb** was filed on April 1, 1987, and issued on November 14, 1989, i.e. more than a year prior to the earliest claimed effective filing date of '502, i.e. July 3, 2008 and thus, is available as prior art under 35 USC 102(b) and 35 USC 103.

Reference (5) to **Dalke** was filed on March 1, 2006, and published on September 21, 2006, i.e. more than a year prior to the earliest claimed effective filing date of '502, i.e. July 3, 2008 and thus, is available as prior art under 35 USC 102(b) and 35 USC 103.

Reference (6) to **Al-Ali** was filed on November 29, 2006, and was published on May 31, 2007, 2006, i.e. more than a year prior to the earliest claimed effective filing date of '502, i.e. July 3, 2008 and thus, is available as prior art under 35 USC 102(b) and 35 USC 103.

Reference (7) to **Cheng** was filed on November 1, 2005, and issued on November 9, 2006, i.e. more than a year prior to the earliest claimed effective filing date of '502, i.e. July 3, 2008 and thus, is available as prior art under 35 USC 102(b) and 35 USC 103.

Reference (8) to **Mao** was filed on May 6, 2008 but published on December 25, 2008, after the earliest claimed effective filing date of '502, i.e. July 3, 2008, and thus, is available as prior art under 35 USC 102(e) and 35 USC 103.

Reference (9) to **Rafert** was filed on October 31, 1996, and issued on October 6, 1998, i.e. more than a year prior to the earliest claimed effective filing date of '502, i.e. July 3, 2008 and thus, is available as prior art under 35 USC 102(b) and 35 USC 103.

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Reference (10) to **Kiani** was filed on March 21, 2005, and was published October 20, 2005, i.e. more than a year prior to the earliest claimed effective filing date of '502, i.e. July 3, 2008 and thus, is available as prior art under 35 USC 102(b) and 35 USC 103.

Reference (11) to **Bernstein** was filed on September 28, 1999, and issued on March 12, 2002, i.e. more than a year prior to the earliest claimed effective filing date of '502, i.e. July 3, 2008 and thus, is available as prior art under 35 USC 102(b) and 35 USC 103.

Reference (12) to **Secker** was filed on January 23, 1991, and issued on February 23, 1993, i.e. more than a year prior to the earliest claimed effective filing date of '502, i.e. July 3, 2008 and thus, is available as prior art under 35 USC 102(b) and 35 USC 103.

Reference (13) to **Tran** was filed on June 30, 2006 but published on January 3, 2008, i.e., after the earliest claimed effective filing date of '502, i.e. July 3, 2008, and thus, is available as prior art under 35 USC 102(e) and 35 USC 103.

Reference (14) to **Goldsmith** was filed on July 31, 2006, and published on April 26, 2007, i.e. more than a year prior to the earliest claimed effective filing date of '502, i.e. July 3, 2008 and thus, is available as prior art under 35 USC 102(b) and 35 USC 103.

Proposed Grounds of Rejection of Claims 19-22 and 28 of 10,912,502

Ground 1:

a) Claims 19-22 and 28 Are Obvious Over Aizawa in view of Rulkov, Numaga, Jaeb, and Goldsmith.

b) Claims 19-22 and 28 Are Obvious Over Aizawa in view of Rulkov, Numaga, Jaeb, Goldsmith and Dalke.

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Ground 2:

a) Claim 19 Is Obvious Over Al-Ali in view Cheng, Mao, and Rafert.

b) Claims 20-21 Are Obvious Over Al-Ali in view Cheng, Mao, Rafert and Bernstein.

c) Claim 22 Is Obvious Over Al-Ali in view Cheng, Mao, Rafert, Bernstein and Secker.

d) Claim 19 Is Obvious Over Al-Ali in view Cheng, Mao, Rafert and Kiani.

e) Claims 20-21 Are Obvious Over Al-Ali in view Cheng, Mao, Rafert, Kiani and Bernstein.

f) Claims 22 Are Obvious Over Al-Ali in view Cheng, Mao, Rafert, Bernstein, Kiani and Secker.

g) Claims 22 Are Obvious Over Al-Ali in view Cheng, Mao, Rafert, Bernstein, Kiani and Tran.

Substantial New Question Of Patentability

For a substantial new question of patentability (SNQ) to be present, it is only necessary that: (A) the prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim, i.e., the teaching of the (prior art) patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and (B) the same question of patentability as to the claim has not been decided by the Office in a previous examination or pending reexamination of the patent or in a final holding of invalidity by the Federal Courts in a decision on the merits involving the claim. *See* MPEP §2242.

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As noted above, during the prosecution of the '407 application, the claims were issued following the December 9, 2020 Notice of Allowance, See **Summary of Prosecution History** section above.

Accordingly, for evaluation of substantial new questions concerning patentability (SNQs) of claims 19-22 and 28, i.e. "the Challenged Claims", it is found that the technical features/elements for which the independent claims, including claims 19 and 28 of the Challenged Claims" were issued as per the December 9, 2020 Notice of Allowance are as follows:

[1] a) four photodiodes arranged on an interior surface of the user-worn device and configured to receive light after attenuation by tissue of the user;

b) a protrusion comprising a convex surface extending over the interior surface,

c) a plurality of openings in the convex surface extending through the protrusion and aligned with the four photodiodes, each opening defined by an opaque surface, and

d) a plurality of windows, each of the windows extending across a different one of the openings ...

in combination with the other claimed elements/ steps.

[2] a) four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;

b) a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material [sic] each opening positioned over a different one[sic] of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue;

c) optically transparent material within each of the openings...

in combination with the other claimed elements/ steps.

[3] a) four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;

b) a thermistor configured to provide a temperature signal;

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c) a protrusion arranged above the interior surface, the protrusion comprising:
a convex surface;

d) a plurality of openings in the convex surface, extending through the
protrusion [sic] and aligned with the four photodiodes, each opening defined by
an opaque surface configured to reduce light piping; and

e) a plurality of transmissive windows, each of the transmissive windows
extending across a different one of the openings;

f) at least one opaque wall extending between the interior surface and the
protrusion, wherein at least the interior surface, the opaque wall and the
protrusion form cavities, wherein the photodiodes are arranged on the interior
surface within the cavities...

in combination with the other claimed elements/ steps..

Claim Interpretation

As set forth in MPEP 2240, in making the determination of whether to order
reexamination, the Office will determine the proper meaning of the patent claims by giving the
claims their broadest reasonable interpretation consistent with the specification (see *In re*
Yamamoto, 740 F.2d 1569 (Fed. Cir. 1984).⁴

Analysis

**Requester asserts Aizawa in view of Rulkov, Numaga, Jaeb, and Goldsmith or
Aizawa in view of Rulkov, Numaga, Jaeb, Goldsmith and Dalke raises a substantial new
question of patentability with regard to claims 19-22 and 28.** See pages 2-6, 32-103 of the
Request.

The **Aizawa, Dalke, and Goldsmith** references were cited during the prosecution of the
‘407 application from which the ‘502 patent issued and were asserted in the non-instituted
‘01273 IPR discussed above. The **Jaeb** reference was cited and discussed for what it taught

⁴ Note Exhibit 1026, 377ITC 1276 , pages 26-33 as originally numbered with regard to the discussion of the terms
“over”/“above” and “opening”/“through openings”.

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alone in the Notice of Allowance discussed above. To the extent such references might be considered “old” art, MPEP 2242 states:

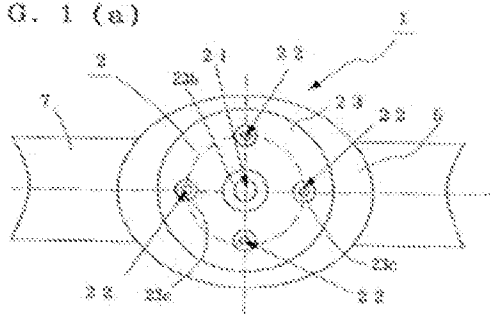
“for example, a substantial new question of patentability may be based solely on old art where the old art is being presented viewed in a new light, or in a different way, as compared with its use in the earlier examination(s), in view of a material new argument or interpretation presented in the request.”

In this instance, Requester asserted such references in combination with **Rulkov and Numaga** which were not previously of record, i.e. presented in a new light/different way.

Accordingly, the **Aizawa, Jaeb, Dalke, and Goldsmith** references are not precluded from raising a substantial new question of patentability as presented.

The primary reference **Aizawa** is generally directed to a “pulse wave sensor for detecting a pulse wave by detecting light output from a light emitting diode and reflected from the artery of a wrist of a subject.” Abstract. **Aizawa’s** pulse wave sensor device can analyze a user’s blood wave by using a central emitter, namely LED 21, to emit light that is picked up by photodiodes, namely photodetectors 22, that are arranged around the LED. [0023]. In one example, “[n]ear infrared radiation output toward the wrist 10 from the light emitting diode 21 is reflected by a red corpuscle running through the artery 11 of the wrist 10 and this reflected light is detected by the plurality of photodetectors 22 so as to detect a pulse wave.” [0027]. Moreover, **Aizawa** discloses, as shown in FIG. 1(a) below, “four photodetectors 22 are disposed around one light emitting diode 21 on a circle concentric to the light emitting diode 21 to detect a pulse wave accurately “even when the attachment position . . . is dislocated.” [0032]. See also Request bridging pages 2-3.

FIG. 1 (a)



Aizawa describes two embodiments, see Figs. 1b and 5 (below), both of which include a holder 23⁵ for storing the light emitting diode 21 and the photodetectors 22 in cavities 23b and 23c formed in a planar detection face 23a. The light emitting face 21s of the light emitting diode 21 and the light receiving faces 22s of the photodetectors 22 are set back or recessed from the above detection face 23a. To expand the light emitting area of the light emitting diode 21 and the light receiving areas of the photodetectors 22, sections of the above cavities 23b and 23c are tapered such that their widths increase toward the contact face. [0023], [0024]. See also page 3, lines 4-7 of the Request.

Additionally, as shown in FIG. 1(b) below, a planar acrylic transparent plate 6, extends over and projects out from the outer casing 5, and thereby face 23a, photodiodes 22 and emitter 21. A belt fastens the plate 6 so that it becomes close to the artery 11 of the wrist 10. Thereby, adhesion between the wrist 10 and the pulse rate detector 1 is improved. [0026], [0034]. In the embodiment relied upon by the Request, FIG. 5, see again below, the holding member 23 itself projects/extends out from the outer casing 5 to define a planar plate also spacing the photodiodes 22 and emitter 22 from the wrist 10 rather than providing the planar acrylic transparent plate 6.

⁵ As discussed below, Numaga describes this support member/holder of Aizawa as being of light shielding/opaque material.

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Aizawa explains that even with such alteration “adhesion can be improved.” [0026], [0034]. See again page 3, lines 4-7 of the Request.

FIG. 1 (b)

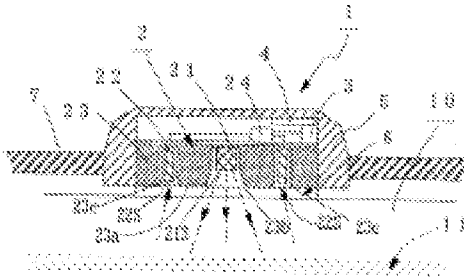
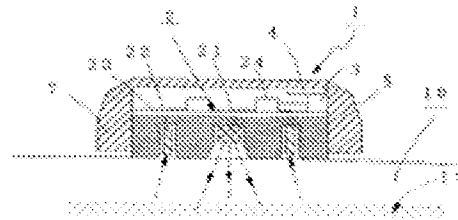
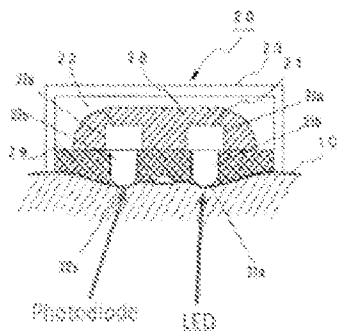


FIG. 5

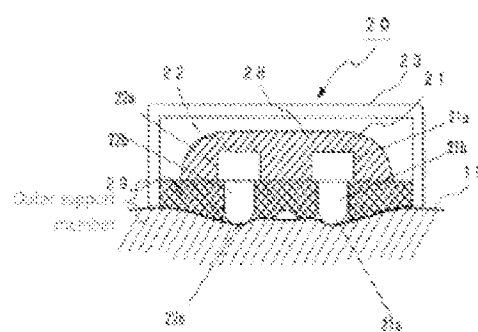


With regard to a [p]rotrusion comprising a convex surface”⁶, the Request presents

Numaga. See Request, pages 3 (footnote 5), 6, 41- 43, and 56, i.e.:

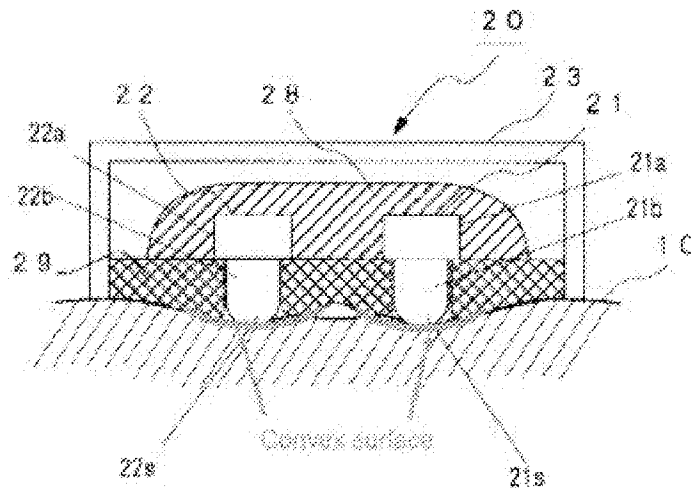


APPLE-1006 (Numaga), FIG. 1(a) (annotated)



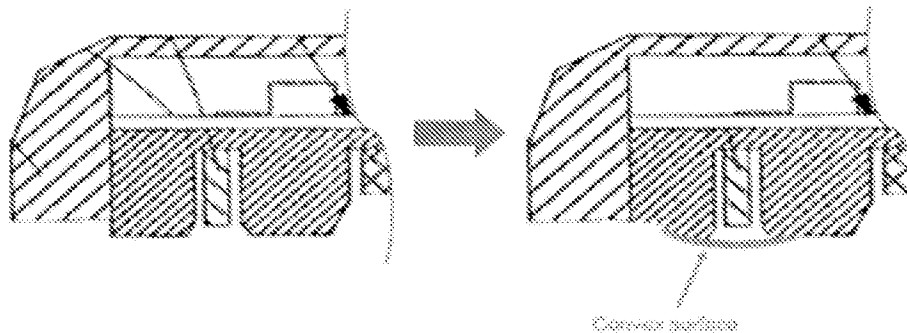
APPLE-1006 (Numaga), FIG. 1(a) (annotated)

⁶ See Technical Features [1]b), [2]b) and [3]c). See also Technical Features [1]c) and [3]d) and f).



APPLE-1006 (Numaga), FIG. 1(a) (annotated)

The Request then asserts “[f]rom this [above annotated Figure] and related description, a POSITA would have found it obvious **to implement the curved/convex protrusion of Numaga** into the Aizawa-Rulkov combination device.” (Emphasis added.) (Pages 56-57 of Request.):

APPLE-1004 (Aizawa), FIG. 5 (modified to include convex surface)¹⁵

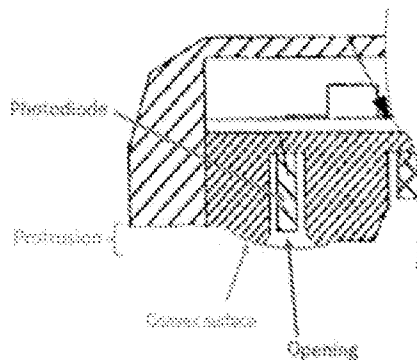
See also Request, pages 3 (footnote 5), 41- 43, 58, 75 and 91-92.⁷

On page 58 the Request sets forth:

... a POSITA would have been motivated to implement a curved bottom surface because this configuration provides better physical contact and enhanced optical coupling between the sensor and the user's tissue, e.g., as compared to a flat bottom surface. APPLE- 1003 (Expert Declaration), ¶75. Numaga itself recognizes such advantage, stating that "[b]ecause the light emitting surface 21s and the light receiving surface 22s *are pressed against the skin . . . , the light path of the near-infrared light is short,*" and "[a]s a result, *sensor sensitivity is much higher* than when the light emitting surface 21s and the light receiving surface 22s are simply brought into contact with the wrist 10." APPLE-1006 (Numaga), [0010], [0011], [0013]. (Emphasis original.)

On pages 76 and 92-93, the Request further asserts:

Moreover, as further illustrated below, the protrusion includes multiple openings each of which is provided through the protrusion and the convex surface and is aligned with a corresponding photodiode. *Id.* Specifically, the holder of Aizawa, which provides the claimed protrusion, is made from an opaque material to shield the detectors from unwanted ambient light coming from outside the housing. See APPLE-1004 (Aizawa), [0012], [0024], FIG. 1(b). Numaga, whose protrusion shape is incorporated into Aizawa's holder, similarly describes a holder that is "covered with a light shielding member." APPLE-1006 (Numaga), [0010]; see also *id.*, [0009]....



APPLE-1004 (Aizawa), FIG. 1 (modified/annotated)

⁷ The Request refers to "Section IX.A.7" while the correct section is VIII.A.7.

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Numaga⁸ recognizes that **Aizawa**⁹ suffers from decreased sensor sensitivity and pulse wave detection accuracy due to a plate projecting from the outer casing 5 to engage the wrist, i.e. interposed between the light emitting element 21 and light receiving element 22 and the wrist. **Numaga**, pages 3-5, [0002]-[0005]. In order to correct such problems, **Numaga** discloses a pulse wave sensor 20 which provides a single light emitting element 21 and a single light receiving element directly engaged with the wrist rather than the plate. As shown in the annotated FIGs. 1a) above, a convex tip 21s of light emitting surface 21 and the convex tip 22s of light receiving element 22 are exposed on the outside of the sensor and come into direct contact with the wrist. Since the tips 21s, 22s protrude, they apply pressure against the skin. In so doing, the sensor sensitivity is improved, **Numaga**, pages 5-7, [0007] (i.e., "...the pulse wave sensor characterized in that a light emitting surface of the light emitting element and a light receiving surface of the light receiving element are exposed on the surface of a sensor case that comes into contact with the wrist. This improves sensor sensitivity because the light emitting element and the light receiving element come into direct contact with the wrist,... the tip of the light emitting element and the tip of the light receiving element protrude toward the wrist. Because the light emitting surface and light receiving surface are closer to blood vessels in the wrist, sensor sensitivity is further improved."), [0009] (i.e., "...In the pulse wave sensor 20 according to the present example, the light emitting surface 21s at the tip of the light emitting element 21 and the light receiving surface 22s at the tip of the light receiving element 22 protrude from the surface of the sensor case 23 in contact with the wrist 14, the light emitting

⁸ The references to **Numaga** refer to the translation of **Numaga**, Exhibit 1006.

⁹ Pages 3-5 of **Numaga** discuss problems regarding Figs. 2(a) and 2(b) of the prior art, referring specifically to "Patent Document 1" which is identified in Paragraph [0004] on page 4 as "[Patent Document 1] JP 2002-360530 A", filed as JP2001-175909. **Aizawa**, discussed above, claims foreign priority on its first page from such JP2001-175909. The Figures of JP 2002-360530 and **Aizawa** are identical.

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surface 21s and the light receiving surface 22s are exposed on the outside of the sensor, ... and when the pulse wave sensor 20 is worn on the wrist 10, the light emitting surface 21s and the light receiving surface 22s surrounded by a light shielding member (outer support member 29) press against the skin.”), [0010] (i.e. “When a pulse wave sensor 20 with this configuration is placed in contact with the wrist 10, the light emitting surface 21s of the light emitting element 21 comes into direct contact with the wrist 10 and presses against the skin. As a result, there is no transmission loss as in the past, and all near-infrared light emitted from the light emitting element 21 in the direction of the wrist 10 is introduced to the wrist 10. Thus, near-infrared light from the light emitting element 21 can be used efficiently. Near-Infrared light emitted from the light emitting element 21 in the direction of the wrist 10 is reflected by the red blood cells flowing through an artery in the wrist 10 (not shown) and enters the light receiving element 22. In the present example, the light receiving surface 22s of the light receiving element 22 is in direct contact with the wrist 10, so there is no transmission loss via a transparent panel, etc., and sensor sensitivity is improved. ... Because the light emitting surface 21s and the light receiving surface 22s are pressed against the skin at this time, the light path of the near-infrared light is short. As a result, sensor sensitivity is much higher than when the light emitting surface 21s and the light receiving surface 22s are simply brought into contact with the wrist 10....”), [0011], and [0013] (i.e., “**Because, as described above, the light emitting surface of the light emitting element and the light receiving surface of the light receiving element constituting the pulse wave sensor are exposed on the surface of the sensor case that comes into contact with the wrist, the light emitting element and the light receiving element come into direct contact with the wrist, As a result, transmission loss can be reduced significantly, sensor sensitivity**

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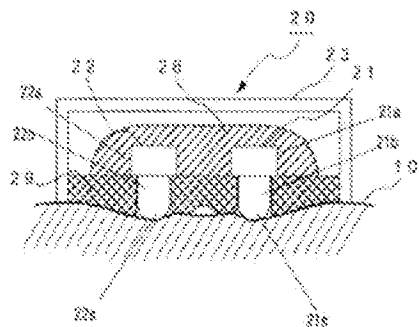
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can be improved, and pulse wave detection accuracy can be improved because unwanted light does not reach the light receiving element....” (bold emphasis added)).

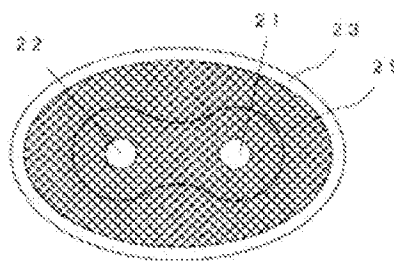
Numaga also describes an outer support member 29 of light shielding material within the sensor casing 23. The area excluding the light emitting surface 21s and the light receiving surface 22s is covered with the outer support member 29. Therefore, the surface of the pulse wave sensor 20 that comes into contact with the wrist 10 is a slightly raised surface consisting of the light emitting surface 21s, the light receiving surface 22s, and the surrounding outer support member 29, and when the pulse wave sensor 20 is worn on the wrist 10, the light emitting surface 21s and the light receiving surface 22s surrounded by a light shielding member (outer support member 29) press against the skin as seen in the Figures below.

(Fig. 1)

(a)



(b)



In so doing, pulse wave detection accuracy can be improved. See also Numaga, pages 5-7, [0008] -[0010], [0011] (i.e., “...Also, because the portions other than the light emitting surface 21s and light receiving surface 22s are covered with an outer support member 29, and the back

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side of the light emitting element 21 and the light receiving element 22 are covered with a light shielding sealing adhesive 28, unwanted light can be kept from reaching the light receiving element 22 and pulse wave detection accuracy can be improved.”), and **[0013]** (i.e. “... **Because the tip of the light emitting element and the tip of the light receiving element protrude toward the wrist, and the portions other than the light emitting surface and light receiving surface are covered with a light shielding member, unwanted light can be kept from reaching the light receiving element and pulse wave detection accuracy can be improved.**” (emphasis added)).

Finally, **Numaga** provides that while in the shown embodiments the pulse wave sensor 20 consisted of a single light emitting element 21 and a single light receiving element 22, the invention can be applied to other types of pulse wave sensors, such as **Aizawa**, in which more than one light receiving element 22 is concentrically and symmetrically arranged around a light emitting element 21. **Numaga**, page 7, **[0012]** (i.e. “...the configuration of the present invention in which the light emitting surface 21s of the light emitting element 21 and the light receiving surface 22s of the light receiving element 22 are exposed on the surface of the sensor case 23 and brought into contact with the wrist 10 is not limited to the configuration in the disk-shaped sensor case 23... and can be realized using various types of sensor cases.”)

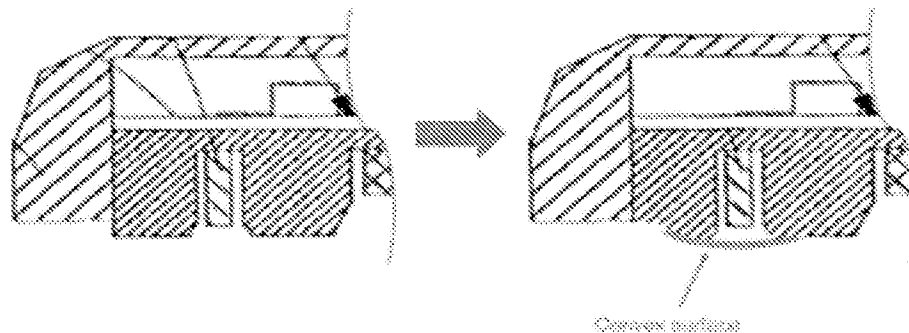
However, contrary to the Request (i.e. “the curved/convex protrusion of Numaga” being “implement[ed]” “into the Aizawa-Rulkov combination device”, pp.56-57), the curved/convex protrusion actually taught by **Numaga** (i.e. the protruding convex tip 22s of the light receiving/photodiode and surrounding light shielding holding member) is not actually

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implemented in the structure postulated by the Request as being the **Aizawa-Rulkov-Numaga** combination.

Aizawa, both before and after modification, as shown below include a photodiode/light receiving element which does not protrude out of the sensor to directly engage with and press against the wrist, i.e. destroys the actual teachings of **Numaga**:



APPLE-1004 (Aizawa), FIG. 3 (modified to include convex surface)¹⁵

As recognized by the Request itself, it is the specific components so forming such curved/convex protrusion, i.e. including the protruding convex light emitting surface 21s and light receiving surface 22s, that provides the combination motivating advantages. See page 58 of the Request again, i.e. "...to implement a curved bottom surface because this configuration provides better physical contact and enhanced optical coupling between the sensor and the user's tissue, e.g., as compared to a flat bottom surface. APPLE- 1003 (Expert Declaration), ¶75. Numaga itself recognizes such advantage, stating that "[b]ecause the light emitting surface 21s and the light receiving surface 22s are pressed against the skin ... , the light path of the near-infrared light is short," and "[a]s a result, sensor sensitivity is much higher than when the light emitting surface 21s and the light receiving surface 22s are simply brought into contact with the wrist 10." (Underlining only added. Bold original in Request.)

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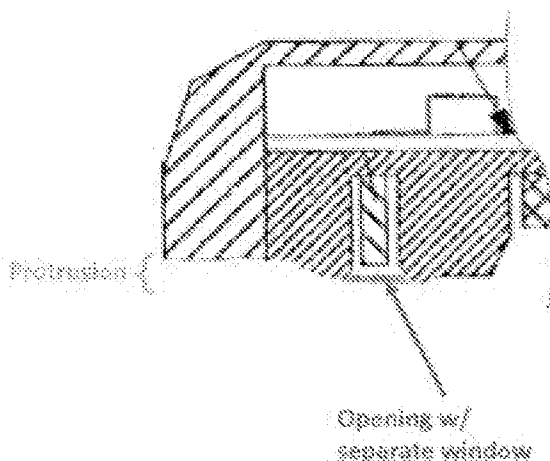
Accordingly, the Request does not implement the structure actually taught by **Numaga** in the postulated **Aizawa-Rulkov-Numaga** combination and thereby, the attendant advantages asserted by the Request as the motivation to combine **Aizawa-Rulkov-Numaga**.¹⁰

Conversely, the implementation of the actual structure taught by **Numaga** as improving **Aizawa**, i.e. protruding photodiode/light receiving element and surrounding light shielding holding member, in the **Aizawa-Rulkov** combination would not provide the structural requirements of the features, i.e. Technical Features [1]-[3] above, for which the independent claims of '502 were issued, e.g. a protrusion comprising a convex surface including separate openings extending through the protrusion ... each opening positioned over a different one of the four photodiodes. See also, e.g., pages 92-93 of the Request again.

In order to further implement windows in openings¹¹ of the postulated **Aizawa/Numaga** “[p]rotrusion comprising a convex surface”, the Request presented **Jaeb**. See Request, pages 3, 43-44 (esp. referencing Jaeb, 5:21-24 “...recessing the LEDs 16, 18 and the detector 20 within the housing and by coating the respective LEDs with a polymer sealant 32.”, and 59, i.e.:

¹⁰ See again, e.g., pages 76 and 92-93 of the Request, i.e. “Specifically, the holder of Aizawa, which provides the claimed protrusion... Numaga, whose protrusion shape is incorporated into Aizawa’s holder...”

¹¹ See Technical Features [1]c) and d), [2]b) and c) and [3]d) and e).



APPLE-1084 (Aizawa), FIG. 5 (modified/annotated)

See also Request, pages 3, 43-44, 59-61, 77, and 93.¹²

The Request set forth (page 60):

A POSITA would have been motivated to dispose such windows across each opening and over the recessed photodiodes and LEDs to isolate these components from contamination from the environment or the tissue, e.g., to provide protection from contaminants like dirt and moisture. See APPLE-1008 (Jaeb), 5:25-27. (Emphasis added.)

Therefore, as discussed above with regard to the postulated combination of **Aizawa** and **Numaga** for implementing a protrusion, the end of the photodiodes/LEDs which are coated as postulated in the modified and annotated Figs. above are recessed entirely within a protrusion housing and isolated from the tissue wrist. Accordingly, the teachings of **Jaeb** and the motivation for its combination with **Aizawa** and **Numaga** are incompatible with the actual structure of **Numaga** and thereby, the attendant advantages asserted by the Request as the motivation for the postulated **Aizawa-Numaga-Jaeb** combination.

Additionally, the postulated structure of the **Aizawa-Rulkov-Numaga-Jaeb** combination shown in such modified/annotated FIGs. above no longer appears to include the convex shape of

¹² See footnote 6.

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the protrusion of the postulated combination of **Aizawa/Numaga**, i.e. the windows in the openings flatten the shape/surface of the protrusion across the openings.

Accordingly, the actual teachings of **Aizawa, Numaga and Jaeb** would not motivate the particular structure of a protrusion with a convex surface including a plurality of openings lined/defined in opaque material with each opening arranged over a different diode and including a window as postulated by the Request. The Request did not assert the remaining references, i.e. **Rulkov, Goldsmith and Dalke**, with regard to these features.

Therefore, and contrary to the assertions of the Request, the combination of **Aizawa Rulkov, Numaga, Jaeb, and Goldsmith** alone or in combination with **Dalke** do not teach or suggest the features/combinations that the prosecution history indicates predicated the allowance of the '502 claims raising a substantial new question of patentability., i.e. Technical Features [1]-[3]. Thus, there is no substantial likelihood that a reasonable examiner would consider the combination of Aizawa, Rulkov, Numaga, Jaeb, and Goldsmith alone or in combination with Dalke important in deciding whether claims 19-22 and 28 of the '502 patent for which reexamination is requested are patentable or not.

Given the teachings of **Aizawa, Rulkov, Numaga, Jaeb, and Goldsmith** alone or in combination with **Dalke** are not found to provide any new technical teachings and do not raise any questions of patentability that have not already been raised and/or addressed during earlier prosecution of the '502 patent, there is no substantial likelihood that a reasonable examiner would consider the combination of **Aizawa, Rulkov, Numaga, Jaeb, and Goldsmith** alone or in combination with **Dalke** important in deciding whether claims 19-22 and 28 of the '502 patent for which reexamination is requested are patentable or not.

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Accordingly, **Aizawa Rulkov, Numaga, Jaeb, and Goldsmith** alone or in combination with **Dalke** do not raise a substantial new question of patentability with respect to claims 19-22 and 28 of the ‘502 Patent.

Requester asserts Al-Ali in view of Cheng, Mao, Rafert alone or in various combinations with Bernstein, Secker, Kiani, and Tran raises a substantial new question of patentability with regard to claims 19-22 and 28. See pages 104-277 of the Request.

The **Al-Ali, Rafert, Bernstein, Kiani, and Tran** references were cited during the prosecution of the ‘407 application from which the ‘502 patent issued. To the extent such references might be considered “old” art, MPEP 2242 states:

“for example, a substantial new question of patentability may be based solely on old art where the old art is being presented viewed in a new light, or in a different way, as compared with its use in the earlier examination(s), in view of a material new argument or interpretation presented in the request.”

In this instance, Requester asserted such references in combination with **Cheng, Secker** and **Mao** which were not previously of record, i.e. presented in a new light/different way.

Accordingly, the **Al-Ali, Rafert, Bernstein, Kiani, and Tran** references are not precluded from raising a substantial new question of patentability as presented.

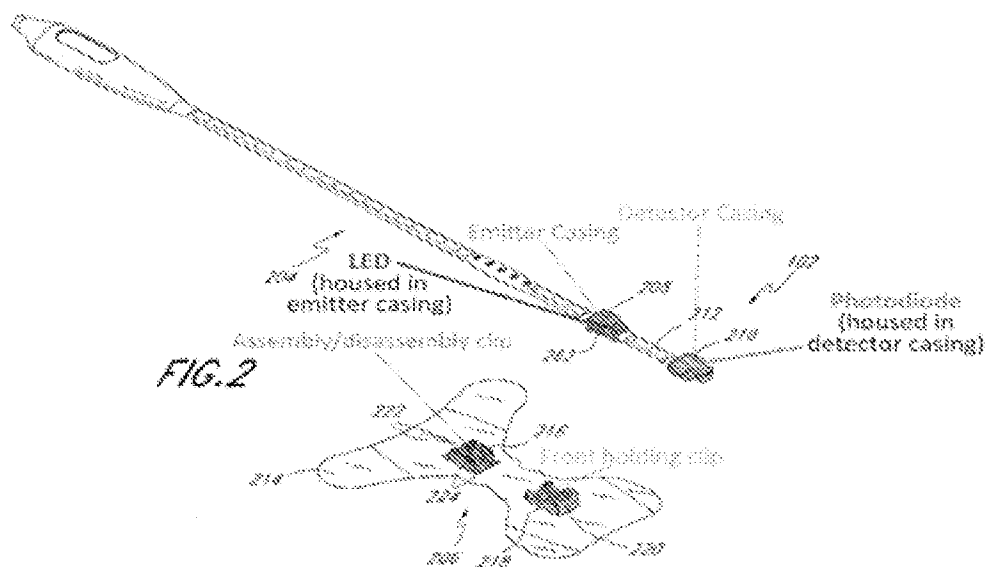
Al-Ali describes a transmittance-type pulse oximeter device that includes “a noninvasive optical sensor or probe” worn on a user’s finger. Abstract, FIG. 4, Claim 1. **Al-Ali** explains that “[p]ulse oximetry—a noninvasive, widely accepted form of oximetry—relies on a sensor attached externally to a patient to output signals indicative of various physiological parameters, such as a patient’s blood oxygen saturation.” [0006]. As set forth in [0008]-[0012], **Al-Ali**

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addresses the need for “for a commercially viable, straightforward, middle-ground solution that offers reusability of expensive electronic components while maintaining some of the advantages of disposable attachment.” [0012]. Therefore, as seen in the annotated FIG. 2 below, **Al-Ali**’s sensor 102 has two main components: (1) a reusable component 204 with “expensive electronic components” such as “the emitters and detector,” and (2) a disposable component 206 “designed to attach the sensor to a measurement site” on a user. [0032], [0034].

Al-Ali’s FIG. 2, and FIGs. 10 and 10B (reproduced below) shows a sensor 102 that has such a reusable component 204 and a disposable component 206. [0048]. The two components 204, 206 can be easily mechanically attached for making a measurement, and then detached after the measurement is complete. [0032]-[0034].



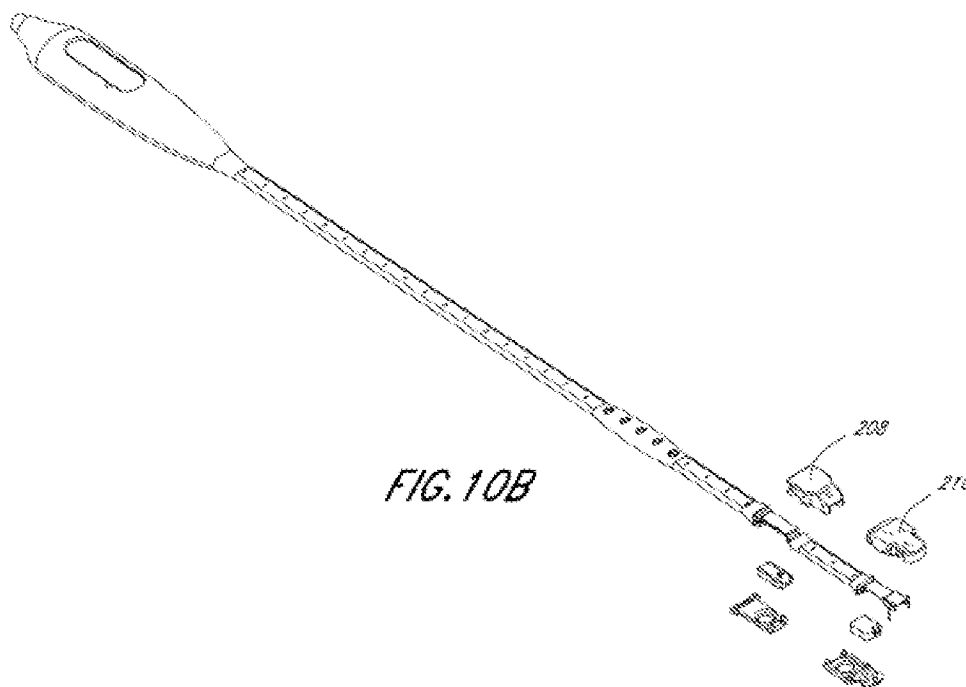
Excerpt from APPLE-1010 (Al-Ali), FIG. 2 (annotated)

The reusable component 204 includes “an emitter casing 208” that includes “one or more emission devices [174] operable to emit light at multiple wavelengths, such as red and infrared.” [0048], [0039]. **Al-Ali** notes that emission devices are typically “specific wavelength emitting

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LEDs,” The reusable component 204 also includes a “[d]etector casing 210 [that] houses one or more detectors [176], such as a photodiode detector.” *Id.* See also FIGs. 3B, 5A-6B. In the exploded view of the reusable portion of FIG. 10B below, both casings 208, 210 of the reusable portion are shown as including lower plates with openings therein. [0028].

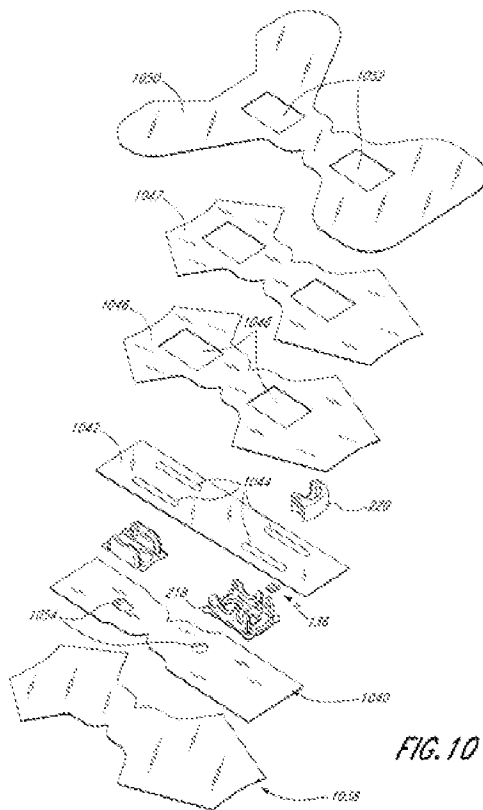


The disposable component 206 includes an assembly/disassembly clip 216 to receive the emitter casing 208, and a front holding clip 218 to receive the detector casing 210. FIGS. 2, 3B, 7-10A. As shown in FIG. 2, the front holding clip 218 protrudes from the exterior surface of a flexible tape base 214 that wraps around a user's finger. **Al-Ali's** front holding clip 218 has an opening 732 that allows light passing through the user's tissue to reach the photodiode(s) of the detector casing 210. [0055], [0059]. The opening 732 can be “a hole through front holding clip 218.” **Al-Ali** also explains that the opening 732 can include a “transparent material” or “material

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allowing free light transmission” to serve as a “window” in the front holding clip 218, which “will allow the sensor to obtain readings while keeping the LEDs and photodiode from becoming contaminated.” [0055], [0059]. In addition, “[o]ther optical filters or the like could also be housed in window 732.” See also elements 944, 946 in Figs. 9 and 12, and paragraphs [0061]-[0063] and Fig. 10 below, e.g. transparent base tape 1038 covering openings 1054.



Al-Ali's sensor wraps around the wearer's finger, so LEDs in an emitter casing 208 at the top of the finger transmits light through the finger (via clip 216 and flexible base 214) to a photodiode/photodiodes in the detector casing 210 (via the flexible base 214 and clip 218) at the bottom of the finger. FIGs. 4, 12, [0048], [0055]. **Al-Ali's** oximeter is connected to a monitor or instrument 172 by a cable 170 and the monitor or instrument 172 includes a processor, e.g.,

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“digital signal processor or microcontroller 192,” to process the sensor signals. FIG. 1, [0039], [0043].

A modified/annotated Fig. 13 of **Al-Ali** is presented multiple times¹³ by the Request. The Request otherwise does not explicitly address the teachings of **Al-Ali** with regard to this Figure. **Al-Ali** describes Fig. 13, like the view shown in Fig. 9, is a “top down” view. [0031], [0059]. In other words, the surface which is exposed/outer when worn is shown in Figure 13.. This view is described in a single paragraph [0068] as “a disposable sensor containing many of the features discussed in this disclosure. Based on the disclosure herein, one of ordinary skill in the art may advantageously fix the components discussed herein to form a disposable sensor without moving beyond the scope of the present disclosure.” Fig. 13 only denotes portions of “a disposable sensor” as 174, i.e. emitters, and 176, i.e. detectors. [0039], Fig. 1. The features/components other than the generally illustrated emitters 174 and detectors 176 forming “a disposable sensor” of the unmodified Fig. 13 are unclear, esp. in light of the discussion in paragraphs [0008]-[0012]. The Request did not resolve this lack of clarity because it does not discuss the unmodified disposable sensor shown in Fig. 13 of Al-Ali. See again, e.g., pages 107-112 of the.

See the Request also at pages 4, lines 4-7, 6, 104-105, 122, 127, 130, 140, 150-151, 157, 157, 165, 168, 169, 186-187 and 207-208 with regard to the asserted features of Al-Ali.

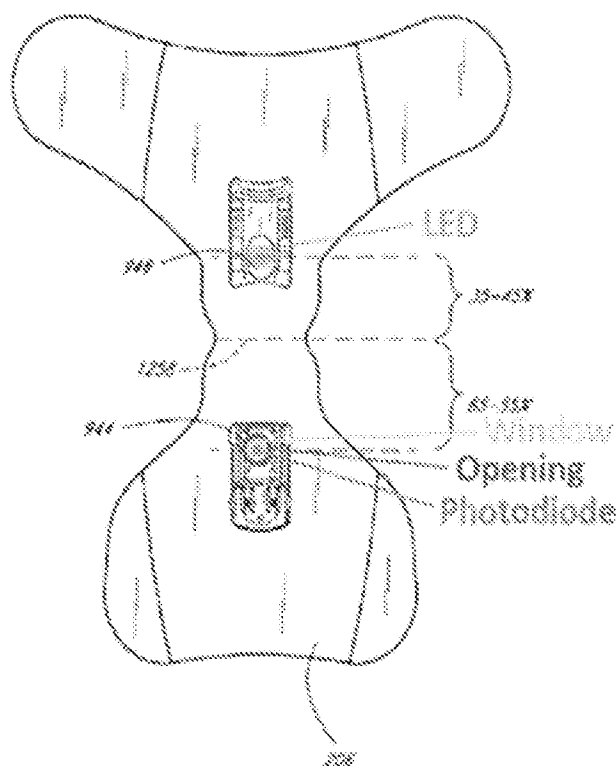
The Request asserts **Al-Ali** “includes one photodiode with a corresponding opening and window...”. Request, page 104. See also page 109 (“The reusable component 204 also includes a ‘[d]etector casing 210 [that] houses one or more detectors, such as a photodiode detector.”

¹³ See, e.g., pages 126, 131, 145, 157, 161, 163, 166, 169 of the Request. Cf. discussion of Ali-Al on, e.g., pages 104-105 and 107-112.

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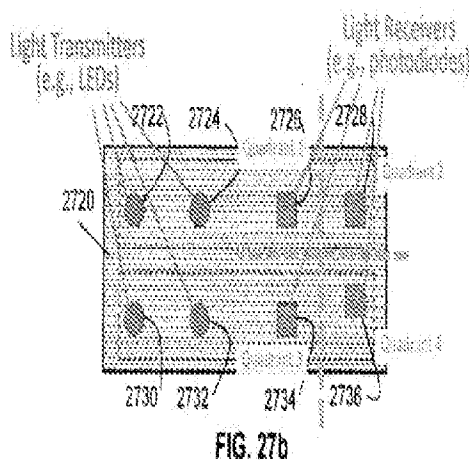
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(emphasis added)) and page 127 (“Al-Ali already discloses a detector casing that ‘houses one or more detectors, such as photodiode detector” (emphasis added)), page 110 (i.e. citing Al-Ali, [0055] and [0059], which describe an opening 732/window 944 aligning with opening 732 which may be a hole or an area of light transmissive material in disposable clip to provide access to one or more detectors of reusable detector casing.) (see also [0039] and [0048)) and page 111 (“Excerpt from APPLE-1010 (Al-Ali), FIG. 12 (annotated)”, see below):

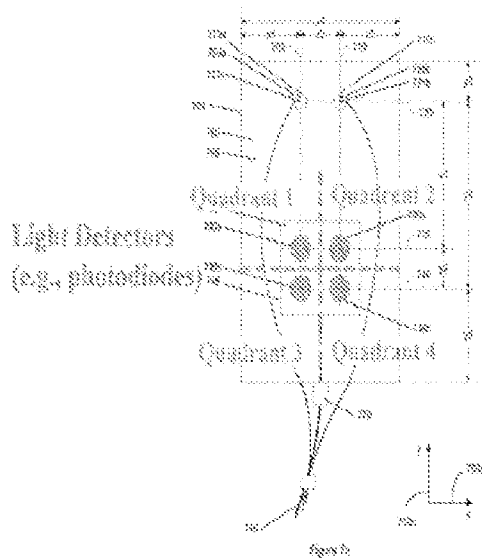


The Request turns to **Chen** and (optionally **Mao**) for implementing “at least four diodes arranged at different quadrants”¹⁴, see pages 105-106 of the Request, e.g.:

¹⁴ See Technical Feature [3]a). Cf. Technical Features [1]a) and [2]a) which don’t require a quadrant configuration.



Excerpt from APPLE-1011 (Cheng), FIG. 27b (annotated)



APPLE-1012 (Mao), FIG. 7a (annotated)

The Request asserts:

Cheng demonstrates the obviousness of modifying a device of the type disclosed by Al-Ali to advantageously feature multiple photodiodes arranged to take measurements at multiple locations and through multiple tissue depths, thereby promoting accuracy and reliability. APPLE-1010 (Al-Ali), FIG. 7, [0055], [0063]; APPLE-1011 (Cheng), FIG. 27b, [0170]. And, as Mao confirms by its disclosure of a similar arrangement ... [Page 4.]

The Request further asserts:

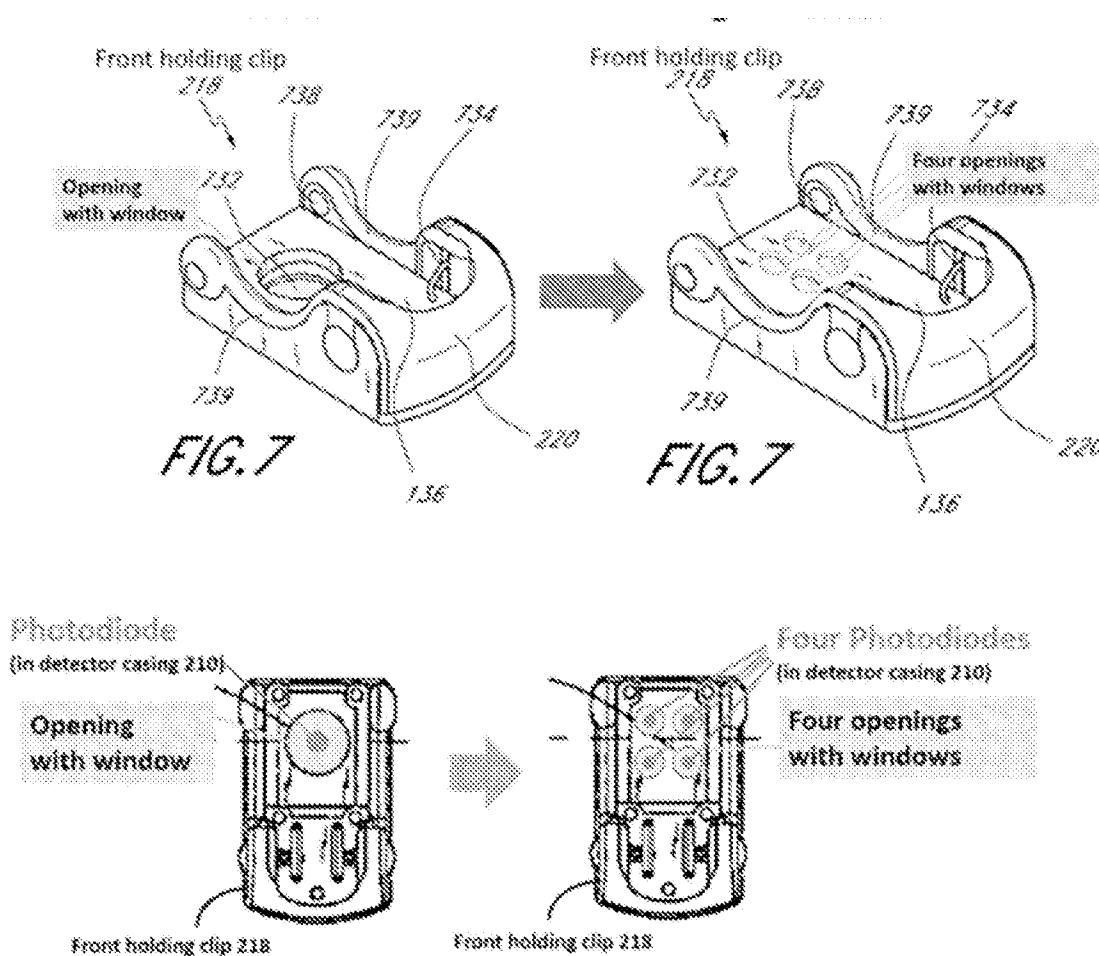
The main difference between Al-Ali and claim 19 is that Al-Ali's device includes *one photodiode* with a corresponding opening and window¹⁵, while claim 19 recites *four photodiodes* each having a corresponding opening and window. It would have been obvious to include four photodiodes in Al-Ali's oximetry sensor based on Cheng, which specifically discloses this configuration to allow measurement of multiple locations of user tissue. APPLE-1011 (Cheng), Fig. 27b, [0170]. This would have been obvious to be able to measure different locations of user tissue without the need to re-position the oximeter, as Cheng teaches, and to improve the overall accuracy and reliability of the sensor. APPLE-1011 (Cheng), [0170], Fig. 27b; APPLE-1003 (Expert Declaration), ¶166. The modifications to Al-Ali's sensor would have been further obvious in view of Mao, which shows four photodiodes that, similar to Cheng, may be "positioned at the vertices of a

¹⁵ However, and as recognized by the Request, Al-Ali's device also describes four diodes, i.e. "one or more diodes", with one corresponding opening and window. See again, e.g. page 109, lines 3-4 and the sentence bridging pages 110-111.

square” or may be “positioned at vertices of any quadrilateral.” APPLE-1012 (Mao), [0167], Fig. 7a (showing photodiode detectors 730a-730d).” [Pages 104-105.]

See also pages 186 and 207 of the Request.

The Request further presents **Al-Ali** and, optionally **Mao**, for implementing the diodes each having separate openings and windows¹⁶, see pages 144-145 (“Al-Ali-Cheng-Mao-Rafert [sic] composite before and after Figures based on APPLE-1010 (Al-Alli)...”, FIGs 7 and 12:¹⁷



¹⁶ See Technical Features [1]a) and d), [2]b) and c) and [3]d) and e).

¹⁷ “The composite figures illustrate the modification from a single photodiode with a single opening and window in Al-Ali to four photodiodes and four openings and windows in the combination. APPLE-1003 (Expert Declaration), ¶248.” [Page 144.] (Emphasis added.)

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With regard to **Al-Ali**, see also page 105 of the Request:

When adding photodiodes to Al-Ali's device, it would have been obvious to replicate Al-Ali's opening-and-window structure for each photodiode, since Al-Ali demonstrates how an opening and window over a photodiode localizes light collection to a particular region of user tissue where measurement is desired. APPLE-1010 (Al-Ali), [0055]; APPLE-1003 (Expert Declaration), ¶166...

and page 140 of the Request:

In Al-Ali's design, an opening and window over a photodiode controls light collection so the photodiode collects light from the specific location of user tissue to be measured. APPLE-1010 (Al-Ali), [0055] (opening 732 controlling the "light energy to be read by the photodiode")¹⁸; APPLE-1003 (Expert Declaration), ¶240. A POSITA would have found it obvious to use this same technique for each of the four photodiodes in the combination, so that each photodiode has an opening and window to localize its light collection to its corresponding measurement location. APPLE-1003 (Expert Declaration), ¶240.

With regard to **Mao**, the Request at page 105-106 further asserts:

Mao also describes that the four photodiodes can each have separate openings and windows. APPLE-1012 (Mao), Fig. 7a, [0128] ("the detectors may each have their own separate opening"), [0142]¹⁹ (window provided as a "light diffusing layer" over some or all detectors), [0146] (light diffusing layer can be "separate pieces that "each has the same shape as the detector structures")²⁰; APPLE-1003 (Expert Declaration), ¶167. [See also page 4, lines 10-15.]

See also pages 143-144, 186 and 208 of the Request.

However, the structure postulated by the Request as being the **Al-Ali-Cheng-Mao combination** (See, e.g., page 143, i.e. "Using a separate opening and window would have been further obvious in view of Mao, which teaches the structure of separate openings and windows for each of four photodiode light detectors." and the after modification illustration above,

¹⁸ See footnote 14.

¹⁹ "[0142] The example in the figure shows two out of the four detector structures covered by the light diffusing layer..."

²⁰ "[0146] **In another implementation, the light diffusing layer may be placed directly on the two detector structures as opposed to being attached to the sensor housing base.** The light diffusing layer may be two separate pieces that each has the same shape as the detector structures. Thus, if the detector structures have a circular shape, then the light diffusing layers may be circular as well." (Emphasis added.)

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showing the separate window pieces that each have the same shape as the photodiode detector structures attached to the disposable clip 218) is inconsistent with the “separate pieces that ‘each have the same shape as the detector structures’” actually taught by **Mao**, see footnotes 19-20 again, i.e. are not placed directly on the photodiodes as opposed to being attached to front holding clip.

For implementing a “[p]rotrusion with a convex surface”²¹ with the four photodiodes and four openings and windows in the postulated **Al-Ali-Chen-(and optionally) Mao** combination discussed above, the Request further presents **Rafert**. See Request pages 4 (footnote 6), 6, 106-107, 132, 208:

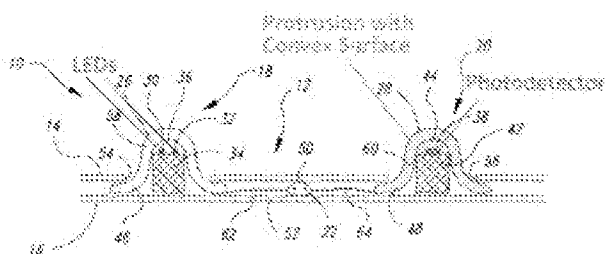


Fig. 2

APPLE-1014 (Rafert), FIG. 2 (annotated)

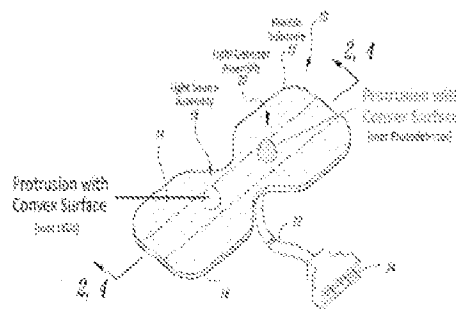


Fig. 1

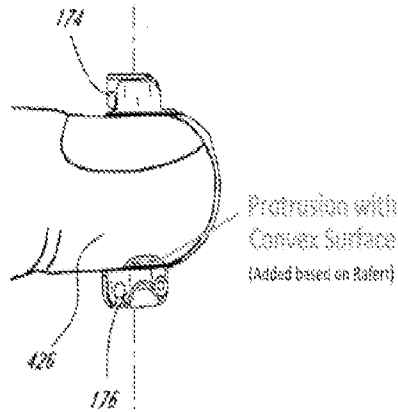
APPLE-1014 (Rafert), FIG. 1 (annotated)

On pages 134-135, 140 and 148, the Request provides “Al-Ali-Cheng-Mao-Rafert combination composite illustration[s]”, see below:

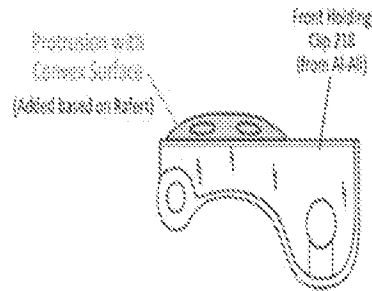
²¹ See Technical Features [1]b), [2]b) and [3]c). Note also Technical Features [1]c), [2]b) and [3]d) and f).

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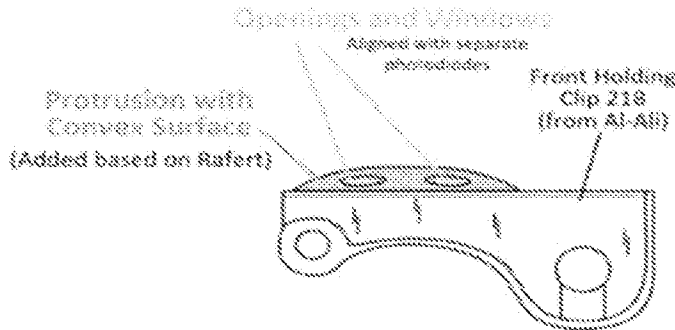
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AI-Ali-Cheng-Mao-Rafert combination composite illustration, based on excerpt from APPLE-1010 (AI-Ali), FIG. 12, modified to show the protrusion added based on APPLE-1014 (Rafert)



AI-Ali-Cheng-Mao-Rafert combination composite illustration, showing a side view with the protrusion added based on APPLE-1014 (Rafert)



See also pages 106-107, 118-122, 132-138, 147-149, 162-165, 208 and 243-244 of the Request.²²

Pages 106-107 of the Request also set forth:

Based on Rafert, it would also have been obvious to include a protrusion having a convex surface at the user's fingertip, *in order to improve the accuracy of oxygen saturation measurements*. APPLE-1014 (Rafert), Abstract, 4:7-58, 3:14-18. Rafert teaches that pulse oximeters are more accurate when a convex protrusion *applies pressure on user tissue at the location where light is collected, and specifically over photodiodes used to measure oxygen saturation at a user's finger*. APPLE-1014 (Rafert), Abstract, 4:7-58, 3:14-18. In particular, Rafert describes a rounded protrusion located over a photodiode light detector assembly 20, where *pressure from the rounded protrusion "affects the*

²² The Request again refers to Section IX rather than Section VIII.

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distributions of blood in the tissues and provides improved accuracy and sensitivity in arterial oxygen saturation measurement, especially in circumstances of low perfusion.” APPLE-1014 Rafert), **FIGS. 1-2**, Abstract; APPLE-1003 (Expert Declaration), ¶168.

(Emphasis added.)

Rafert describes a pulse oximetry sensor 10 that is worn on a user’s finger and is configured to apply stress on user tissue “to afford greater accuracy of measurement.” 3:14-18.

Using light source and light detector assemblies which are constructed to have a high aspect ratio relative to a flexible substrate, “[w]hen the sensor is conformably applied to the patient’s body portion, localized pressure is exerted on the body portion at the points of contact with the light source and light detector assemblies, thereby stressing the skin and the underlying blood-perfused tissue. The stress imparted to the skin and underlying tissues affects the distributions of blood in the tissues and provides improved accuracy and sensitivity in arterial oxygen saturation measurement, especially in circumstances of low perfusion.” Abstract.

Rafert’s sensor 10 includes a “flexible substrate 12, such as an elastic bandage-type material” that can conform to the user’s finger. FIG. 1, 3:26-42. The sensor 10 has a light source assembly 18 and a light detector assembly 20 attached to and that extend from the flexible substrate 12 toward the user’s finger. FIG. 1, 3:43-62. The light source assembly 18 and **the light detector assembly 20 have a high aspect ratio relative to the flexible substrate so as to “project a substantial distance from the inner surface 14 of the flexible substrate 12” so they can “press into the skin” of the patient**. FIG. 1, 3:43-55 (emphasis added).

As shown in annotated FIG. 2 and also Fig. 4 below, **the source and detector assemblies 18, 20 project from the flexible substrate 12 a distance that is not less than**

approximately the distance they extend along the substrate-i.e., having an aspect ratio relative to the flexible substrate of not less than approximately 1:1. 3:56-62.

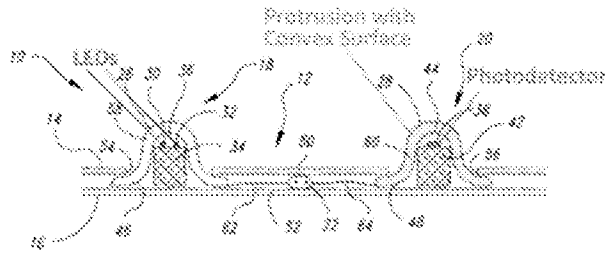


Fig. 2

APPLE-1014 (Rafert), FIG. 2 (annotated)

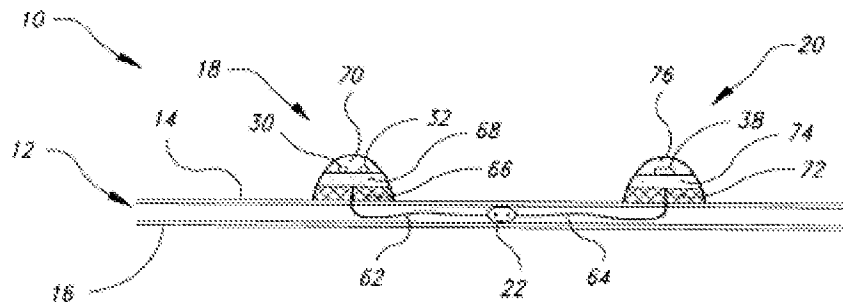


Fig. 4

Each of the source and detector assemblies 18, 20 having such a high aspect ratio relative to the flexible substrate is a rounded projection 26, 28 with a convex surface, 58, 60, formed of a transparent material. 4:59-67, 5:22-27, claims 4-5 and 8. **Rafert** explains that the light detector assembly 20 in Fig. 2 includes a “rigid transparent housing” 28 that provides “firm pressing engagement” between the light detector assembly and the patient's body and encloses the components of the light detector 38. 4:59-67, 2:48-52. The rigid transparent housing 28 normally encloses a single light detector with the detector below the peak

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of the convex surface as shown above. 3:66-4:1, 5:8-10. The detector 38 may also be further encased in a protective silicone covering 44 in the housing. 5:13-15.

In Figure 4, the flexible substrate is either a single layer or a two layers. 5:62-65. The **light detector assembly 20** includes a flexible support pad 72, such as a soft foam pad, **attached to the inner surface 14 of the flexible substrate 12**. 5:13-24. The electric wires 64 pass through the support pad 72 and connect to a substantially rigid photodetector holder, such as a printed circuit board 74. Id. A **transparent rounded protective cover**, such as a silicone cap 76, **which encloses the photodetector 38, exerts localized pressure on the patient's body portion when the sensor 10 is placed in physical conformance therewith** encloses the photodetector 38. 6:13-24, claims 8 and 25.

Rafert sets forth “[t]he high aspect ratio of the light source and light detector assemblies 18, 20 provides a number of distinct advantages over prior art pulse oximetry sensors. “Some conventional pulse oximetry sensors, ...do not apply pressure to the patient's body portion at the points of contact with the light source and/or light detector to achieve optimum performance..., when the sensor 10 is placed in substantial physical conformance with the patient's body portion, **the light source and light detector assemblies 18, 20 each project a substantial distance from the inner surface 14 of the flexible substrate 12 into firm pressing, engagement with the patient's body portion. By exerting pressure at the points of contact, localized stress is imparted** to blood-perfused tissue beneath the light source and detector assemblies 18, 20. **This localized stress forces some of the blood from the blood-perfused tissues adjoining the points of contact.** Because a patient's arterial blood is at a higher pressure than the venous blood, **a greater quantity of venous blood will be removed.**

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This removal of venous blood correspondingly decreases associated light attenuation effects and thereby increases the amount of light reaching the light detector assembly 20, from which the measurements of arterial blood oxygen saturation levels are determined. **Also, because the venous blood has been largely depleted from the transilluminated body portion,** any localized pulse effects in the veins (due to pulsatile distention of adjacent arteries) is minimized. This is particularly advantageous since arterial oxygen saturation is of primary clinical interest. When the patient's heart beats, there is a momentary increase in the arterial pressure and a corresponding increase in arterial blood quantity, thereby causing a momentary decrease in the amount of light received at the light detector assembly 20, from which the patient's pulse is determined. **The localized pressure exerted by the light source and detector assemblies 18, 20 partially depletes the tissue portions adjacent to the assemblies of blood.** These tissue portions then become more and less depleted of blood as a function of the heartbeat cycle, thereby enhancing the alternating component of the light received at the light detector assembly 20. Also, a boundary region separating the blood-depleted tissue portions from the surrounding blood-perfused tissue portions changes position as a function of the heartbeat cycle and creates a shutter-like effect, which further enhances the alternating component of the light received at the light detector assembly 20. The enhanced amplitude of the alternating component provided by the sensor 10 affords improved reliability, accuracy, and sensitivity in arterial oxygen saturation measurement. This is especially advantageous when arteries are constricted, as when dealing with low perfusion states.” (Emphasis added.) 4:7-58.

Rafert also teaches “**the light source and light detector assemblies 18, 20** may be constructed in any of a wide variety of ways and in a variety of shapes, but **all having a high aspect ratio relative to the flexible substrate 12 sufficient to provide the attendant localized**

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pressure on a patient's body portion **to achieve the advantages described above.**" 6:42-48.

(Emphasis added.)

Rafert further explains that **the cover portion 60** of the projecting rigid transparent housing 28/photodetector 38 is "**preferably rounded** so as to minimize any shearing effects when applied to a patient's skin. **This shape also provides a smooth boundary transition from the blood-depleted tissue portions to the surrounding blood-perfused tissue portions**, which enhances the mobility of the boundary region in response to the heartbeat cycle." (Emphasis added.) As a result of the rounded or convex shape "the amplitude of the alternating component of the light received at the light detector assembly 20," is enhanced, which as discussed above, provides "improved reliability, accuracy, and sensitivity" of oxygen saturation measurements. 5:25-33, 4:42-58.

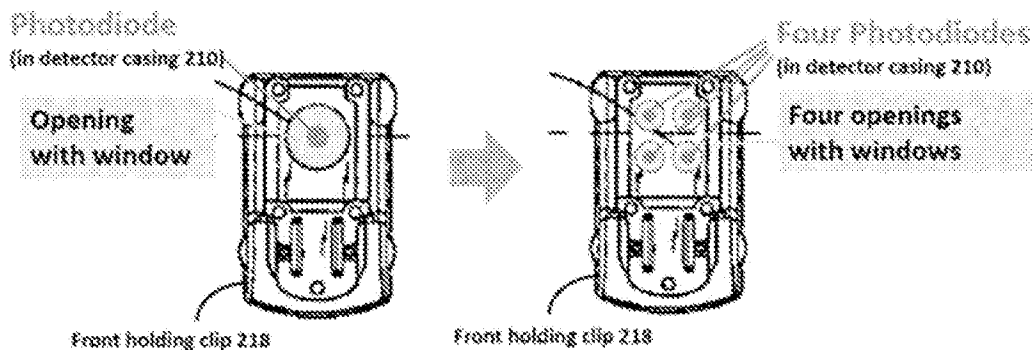
However, contrary to the Request (i.e., "it would also have been obvious to include a protrusion having a convex surface" "[b]ased on Rafert" "into the Al-Ali-Cheng-Mao combination", see again pp.106-107), the protrusion having a convex surface actually taught by **Rafert**--i.e. a light detector assembly projecting from the inner surface of a flexible attachment substrate a specific distance- a high aspect ratio relative to the flexible substrate- which detector housing is a rounded projection, i.e. 28, with a convex surface, i.e. cover 60, formed entirely of a transparent/light transmissive material and encloses a photodetector (normally one) beneath the peak tissue contact point of the convex surface-- is not actually implemented in the structure postulated by the Request as being the **Al-Ali-Cheng-Mao** combination.

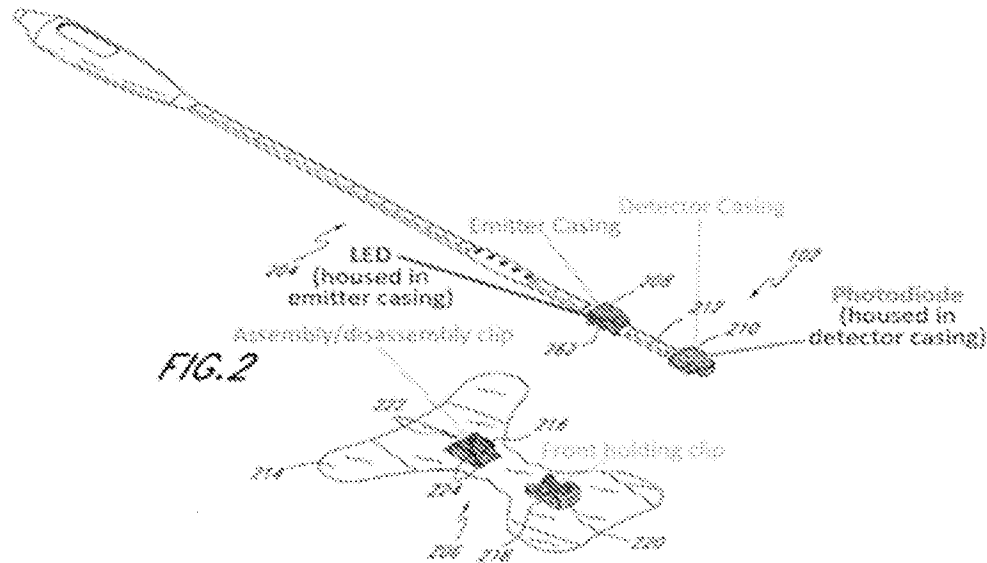
Instead, the postulated **Al-Ali-Cheng-Mao-Rafert** combination, as shown below, includes a reusable detector assembly 210 which contains/encases the four photodiodes in

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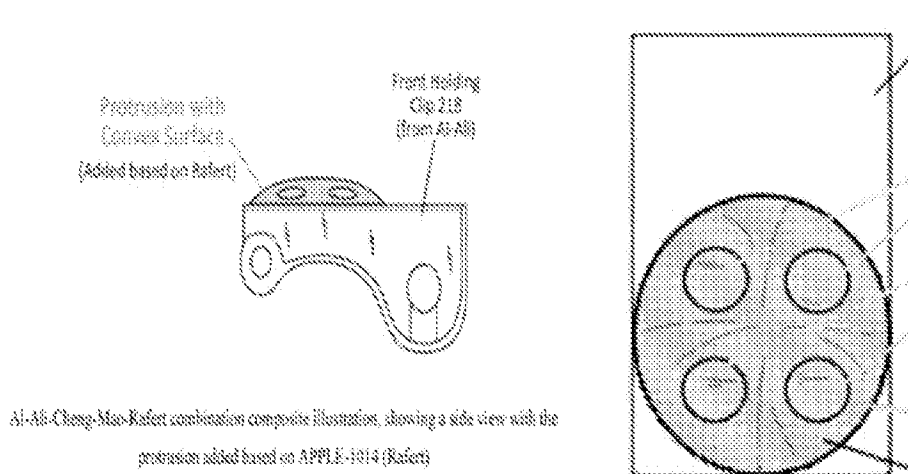
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quadrant configuration attached to a disposable rigid front clip 218/flexible substrate 214. The clip/substrate is interposed between the detector assembly 210 and the patient's body, i.e. the detector assembly does not directly contact and press the patient's body. Furthermore, the postulated protrusion is added to the front clip 218/substrate rather than defined the detector assembly 210 and the aspect ratio of such protrusion relative to the clip/substrate is not addressed. The postulated protrusion/convex surface of the front clip/substrate also includes only four distinct openings/windows for light transmission. These transmissive portions of the protrusion surface/boundary are spaced radially from the peak tissue contact point of the protrusion and thereby, are formed as part of the shape transitioning from the peak contact point apex to the surrounding base connected to the clip/substrate, i.e. positioned over "the surrounding blood-perfused tissue portions" rather than "the blood-depleted tissue portions" at the peak contact point. See pages 109, 140, 145, and 148-149 of the Request.





Excerpt from APPLE-1010 (Al-Ali), FIG. 2 (annotated)



As recognized by the Request itself, it is the light detector assembly 20/rounded protrusion with convex cover and photodetector/protrusion with a convex surface as actually taught by **Rafert**, discussed above, that provides the advantages motivating the postulated combination. See, e.g., pages 106-107 of the Request again (i.e. “In particular, Rafert describes a rounded protrusion located over a photodiode light detector assembly 20, where pressure from

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the rounded protrusion “affects the distributions of blood in the tissues and provides improved accuracy and sensitivity in arterial oxygen saturation measurement, especially in circumstances of low perfusion.”).

Accordingly, the Request does not implement the structure actually taught by **Rafert** in the postulated **Al-Ali-Cheng-Mao-Rafert** combination and thereby, the attendant advantages asserted by the Request as the motivation to combine **Al-Ali-Cheng-Mao-Rafert**, i.e. destroys the teachings of Rafert.

Conversely, the implementation of the protrusion having a convex surface actually taught by **Rafert** as discussed above in the postulated **Al-Ali-Chen-(and optionally) Mao** combination would not provide the structural requirements of the features, see Technical Features [1]-[3] above, for which the independent claims of ‘502 were issued, i.e. a protrusion comprising a convex surface including separate openings with windows²³ extending through the protrusion, each positioned over a different one of the four photodiodes or four photodiodes arranged in different quadrants. Such implementation would also destroy the teachings of Al-Ali by, e.g., placing the light detector assembly between the substrate 214 and the patient’s body in order to

²³ E.g., page 139 of the Request asserts, “If the front holding clip 218 were transparent, no opening 732 or distinct window of transparent material would be needed to allow light to pass through the front holding clip 218.” Similarly, if a protrusion comprising a convex surface is transparent as taught by Rafert, it would follow no openings or distinct windows of transparent material are needed. Therefore, the motivation for adding Rafert’s protrusion which is transparent with the Al-Ali-Cheng-Mao combination as postulated on page 107 of the Request also doesn’t follow, i.e. “Rafert teaches that the convex surface should be located over photodiodes, which, in the Al-Ali-Cheng-Mao-Rafert combination, is the location on the front holding clip 218 where Al- Ali and Mao teach that openings and windows should be placed to direct light to the photodiodes. ... Because Rafert teaches that the convex surface should be at the same location where the openings and photodiodes are located—the fingertip where oxygen saturation is measured—it would have been obvious for the openings taught by Al-Ali and Mao to extend through the convex surface of the protrusion in the Al-Ali- Cheng-Mao-Stivoric[sic]-Rafert combination.”

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press directly thereagainst rather than spaced from the patient's body to prevent sensor contamination as desired. See Al-Ali, e.g., [0055] and [0049].

The Request further postulates that “[i]n the Al-Ali-Cheng-Mao-Rafert combination, the protrusion and convex surface added based on Rafert are formed of the same opaque material²⁴ as the front holding clip 218, which yields a ‘rigid’ surface that can provide the ‘firm pressing 122’”, also based on Al-Ali. See Request, pages 138-139 as well as page 208.

However, as discussed above with regard to adding a protrusion and convex surface based on **Rafert**, the implementation of the actual structure taught by **Rafert** would not add a protrusion to the front holding cli of opaque material. See also footnote 23 again.

Accordingly, the actual teachings of **Al-Ali**, **Cheng**, **Mao**, and **Rafert** would not motivate the particular structure of a protrusion with a convex surface including a plurality of openings lined/defined in opaque material with each opening arranged over a different diode and including a window as postulated by the Request. The Request did not assert the remaining references, i.e. **Bernstein**, **Secker**, **Kiani**, and **Tran**, with regard to these features.

Therefore, and contrary to the assertions of the Request, the combination of **Al-Ali**, **Cheng**, **Mao**, and **Rafert** alone or in various combinations with **Bernstein**, **Secker**, **Kiani**, and **Tran** do not teach or suggest the features/combinations that the prosecution history indicates predicated the allowance of the ‘502 claims raising a substantial new question of patentability. i.e. Technical Features [1]-[3]. Thus, there is no substantial likelihood that a reasonable examiner would consider the combination of **Al-Ali**, **Cheng**, **Mao**, and **Rafert** alone or in various

²⁴ See Technical Features [1]c), [2]b) and [3]d). Note also Technical Feature [3]f).

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combinations with **Bernstein, Secker, Kiani, and Tran** important in deciding whether claims 19-22 and 28 of the '502 patent for which reexamination is requested are patentable or not.

Given the teachings of **Al-Ali, Cheng, Mao, and Rafert** alone or in various combinations with **Bernstein, Secker, Kiani, and Tran** are not found to provide any new technical teachings and do not raise any questions of patentability that have not already been raised and/or addressed during earlier prosecution of the '502 patents, there is no substantial likelihood that a reasonable examiner would consider the combination of **Al-Ali, Cheng, Mao, and Rafert** alone or in various combinations with **Bernstein, Secker, Kiani, and Tran** important in deciding whether claims 19-22 and 28 of the '502 patent for which reexamination is requested are patentable or not.

Accordingly, **Al-Ali, Cheng, Mao, and Rafert** alone or in various combinations with **Bernstein, Secker, Kiani, and Tran** do not raise a substantial new question of patentability with respect to claims 19-22 and 28 of the '502 Patent.

35 USC 325(d)

35 U.S.C. § 325 (d) On April 12, 2024, Patent Owner filed a combined petition Under 37 C.F.R. §§ 1.183 and 1.182 to deny this instant ex parte Reexamination Request Under 35 U.S.C. § 325(d). On April 26, 2024, Third Party Requester filed an Opposition to Patent Owner's April 12, 2024 petition. On May 3, 2024, the Office issued a decision which granted Patent Owner's April 12, 2024 1.183 petition to waive the rules to the extent necessary to permit entry and consideration of Patent Owner's 325(d) arguments in the April 12, 2024 petition by the

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Examiner in making a determination on the Request for reexamination of the '502 patent. Since, the Request for reexamination has been denied on the merits for the reasons set forth above, Patent Owner's arguments relating to a discretionary denial of reexamination pursuant to 35 USC 325(d) are moot and will not be addressed.

Conclusion

Therefore, as a substantial new question of patentability is not present, reexamination is denied, see MPEP 2242. Claims 1-3, 5-7, 9-11, and 13-15 will not be reexamined.

Correspondence

All correspondence relating to this *ex parte* reexamination proceeding should be directed:

By Mail to: Mail Stop *Ex Parte* Reexam
Central Reexamination Unit
Commissioner for Patents
United States Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
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Any inquiry concerning this communication should be directed to the Central Reexamination Unit at telephone number 571-272-7705.

Other useful telephone numbers:

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Supervisory Patent Examiner, Art Unit 3992



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/019,449	03/13/2024	10945648	50095-0044RX1	4484
64735 7590 05/30/2024 Knobbe, Martens, Olson & Bear, LLP MASIMO CORPORATION (MASIMO) 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER SAADAT, CAMERON	
			ART UNIT	PAPER NUMBER
			3992	
			MAIL DATE	DELIVERY MODE
			05/30/2024	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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***EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM**

REEXAMINATION CONTROL NO. 90/019,449 .

PATENT UNDER REEXAMINATION 10945648 .

ART UNIT 3992 .

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Denying Request For Ex Parte Reexamination	Control No. 90/019,449	Patent Under Reexamination 10945648	
	Examiner Cameron Saadat	Art Unit 3992	AIA (FITF) Status No

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed 03/13/2024 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) ☐ PTO-892, b) ☒ PTO/SB/08, c) ☐ Other: _____

The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

- a) ☐ by Treasury check or,
- b) ☒ by credit to Deposit Account No. 06-1050 , or
- c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C.303(c)).

		/Karin Reichle/ Primary Examiner, Art Unit 3992	
cc: Requester (if third party requester)			

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ORDER DENYING EX PARTE REEXAMINATION

A substantial new question of patentability affecting claims 8, 12, 20, 24, and 30 of United States Patent Number 10,945,648 has not been raised by the request for *ex parte* reexamination.

References Asserted by Requester as Raising Substantial New Question of Patentability

- Aizawa et al. – US 2002/0188210 (hereinafter “Aizawa”)
- Rulkov et al. – US 7,468,036 (hereinafter “Rulkov”)
- Numaga et al. – Certified translation of Japanese Patent Application JP2003201849A (hereinafter “Numaga”)
- Jaeb et al. – US 4,880,304 (hereinafter “Jaeb”)
- Dalke et al. – US 2006/0211924 (hereinafter “Dalke”)
- Al-Ali et al. – US 2007/0123763 (hereinafter “Al-Ali”)
- Cheng et al. – US 2006/0253007 (hereinafter “Cheng”)
- Mao et al. – US 2008/0316488 (hereinafter “Mao”)
- Stivorc et al. – US 2005/0245839 (hereinafter “Stivorc”)
- Rafert et al. – US 5,817,008 (hereinafter “Rafert”)
- Matheson – US 7,569,807 (hereinafter “Matheson”)
- Kiani – US 2005/0234317 (hereinafter “Kiani”)
- Hannula et al. – US 8,452,364 (hereinafter “Hannula”)
- Dorogusker et al. – US 2008/0076972 (hereinafter “Dorogusker”)

Summary of Prosecution History

Claims 8, 12, 20, 24, and 30 being requested for reexamination are current claims in US 10,945,648 (hereinafter “the ‘648 Patent”) that issued March 16, 2021 from application 17/031,316 filed September 24, 2020 (hereinafter “the ‘316 application”).

During prosecution the Examiner issued the following statement of reasons for allowance:

The following is an examiner’s statement of reasons for allowance: The filed terminal disclaimer was approved on 11/19/2020 to resolve potential double patenting issues.

In regard to related arts, **Thalmann (USPN 4,129,124 – applicant cited)** teaches a pulse-rate device (Figs. 1-2) comprises a light source (element 9, Fig. 2), a photosensitive element (element 10, Fig. 2), a plurality of recesses (recesses 11 and 12, Fig. 2) with translucent plugs (elements 13, Figs. 1-2), a protrusion (element 6, Figs. 1-2) with a convex surface (surface of element 6, Fig. 1) and opaque material (element 14, Fig. 2). **Jaeb et al. (USPN 4,880,304 – applicant cited)** teaches an optical sensor for pulse oximeter (Figs. 3a-3b) comprising LEDs (elements 16 and 18, Figs. 3a-3B) and a photodetector (element 20, Figs. 3a-3B) disposed on the interior of the housing (element 12, Fig. 3b); a protrusion (protruded portion in the bottom area, Fig. 3b) with a plurality of openings extending through the protrusion (openings/ recesses containing elements 16, 18 and 20, Fig. 3b) and each of the openings containing polymer sealant (element 32, Fig. 3b). **Haar et al. (USPN 5,893,364)** teaches an apparatus for analyte measurements (Figs. 1-2) comprises a LED (element 20, Figs. 1-2) and photodiodes (elements 21, Figs. 1-2); a protrusion (elements 4 and/or 22/23, Fig. 2) with a plurality of openings extending through the protrusion and aligning with the photodiodes (elements 23a, 23b, 23c and 24, Fig. 2) and the remaining surface of the protrusion consists of black paint (Fig. 2 and Col 4 lines 49-61). **Sawada et al. (USPN 8,352,003)** teaches a biosensor (Figs. 2-3) comprises a light emitter (element 21, Figs. 2-3) and light receiving elements (elements 28, Figs. 2-3) disposed on the interior surface of a housing (Figs. 2-3); and a protrusion (light shielding substrate 27 and/or a transparent plate 29, Figs. 2-3), wherein the transparent plate comprises a convex surface for directing the emitted light from the light emitter (element 25, Figs. 2-3) and the light shielding plate comprises a plurality of openings/ windows (pinholes or waveguides 26 with in the light shielding plate 27, Figs. 2-3). However, the prior art of record does not teach or suggest “four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user and a protrusion comprising a convex surface and a plurality of openings extending through the protrusion, the openings arranged over the photodiodes and configured to allow light to pass through the protrusion to the photodiodes”; “a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength; a second set of LEDs spaced

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apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength; four photodiodes arranged on a surface and configured to receive light after at least a portion of the light has been attenuated by tissue of a user; a protrusion arranged above the surface, the protrusion comprising a convex surface and windows, the windows extending across the four photodiodes, wherein light passes through the protrusion to the four photodiodes via at least the windows; a thermistor configured to provide a temperature signal; and one or more processors configured to: receive one or more signals from at least one of the at least four photodiodes; receive the temperature signal; and adjust operation of the user-worn device responsive to the temperature signal”; “a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength; a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength; four photodiodes; a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material; a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes; a separate optically transparent window extending across each of the openings”; and “a plurality of light emitting diodes (LEDs); at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user; a protrusion comprising a convex surface and a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes”, in combination with the other claimed elements/ steps.

(See the ‘316 application, NOA mailed 12/11/2020 p. 2-5)

Based on review of the prosecution history of the ‘316 application and the allowable features emphasized in the reasons for allowance, the following *allowable features* are highlighted below with respect to independent patent claims 8 and 20 and their respective SNQ analysis:

Claim 8. A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:
a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;
a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
four photodiodes;
a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;
a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes;
a separate optically transparent window extending across each of the openings;
one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user;
a housing; and
a strap configured to position the housing proximate tissue of the user when the device is worn.

Claim 20. A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:
a plurality of light emitting diodes (LEDs);
at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user;
a protrusion comprising a convex surface and a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes; and
one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user.

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Summary of Inter Partes Reviews (IPRs) of the '648 Patent

1. IPR2022-01275 proposed grounds of rejection (institution denied):

F. ASSERTED GROUND OF UNPATENTABILITY

Petitioner challenges the patentability of claims 1–30 of the '648 patent on the following grounds (Pet. 6–7):

Claims Challenged	35 U.S.C. §	Reference(s)
1, 2, 4, 5	103	Mendelson-799, Aizawa, Ohsaki
3, 20, 21–30	103	Mendelson-799, Aizawa, Ohsaki, Scharf
6–16, 19	103	Mendelson-799, Aizawa, Ohsaki, Scharf, Dalke, Goldsmith
17	103	Mendelson-799, Aizawa, Ohsaki, Scharf, Dalke, Goldsmith, Bergey
18	103	Mendelson-799, Aizawa, Ohsaki, Scharf, Dalke, Goldsmith, Anderson
1, 2, 4, 5	103	Mendelson-799, Aizawa, Kotanagi
3, 20, 21–30	103	Mendelson-799, Aizawa, Kotanagi, Scharf
6–16, 19	103	Mendelson-799, Aizawa, Kotanagi, Scharf, Dalke, Goldsmith
17	103	Mendelson-799, Aizawa, Kotanagi, Scharf, Dalke, Goldsmith, Bergey
18	103	Mendelson-799, Aizawa, Kotanagi, Scharf, Dalke, Goldsmith, Anderson

(IPR2022-01275 Denying Institution of IPR, paper 15, p. 10)

2. IPR2022-01276 proposed grounds of rejection (institution denied):

F. ASSERTED GROUND OF UNPATENTABILITY

Petitioner challenges the patentability of claims 1–30 of the '648 patent on the following grounds (Pet. 4):

Claims Challenged	35 U.S.C. §	Reference(s)
8, 9	103	Lumidigm, Scharf, Kotanagi
1–7, 10, 12–17, 19, 20–30	103	Lumidigm, Scharf, Kotanagi, Tran

Claims Challenged	35 U.S.C. §	Reference(s)
11	103	Lumidigm, Scharf, Kotanagi, Tran, Forstall
18	103	Lumidigm, Scharf, Kotanagi, Anderson

(IPR2022-01276 Denying Institution of IPR, paper 15, p. 9-10)

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Summary of Substantial New Questions of Patentability Proposed in the Request

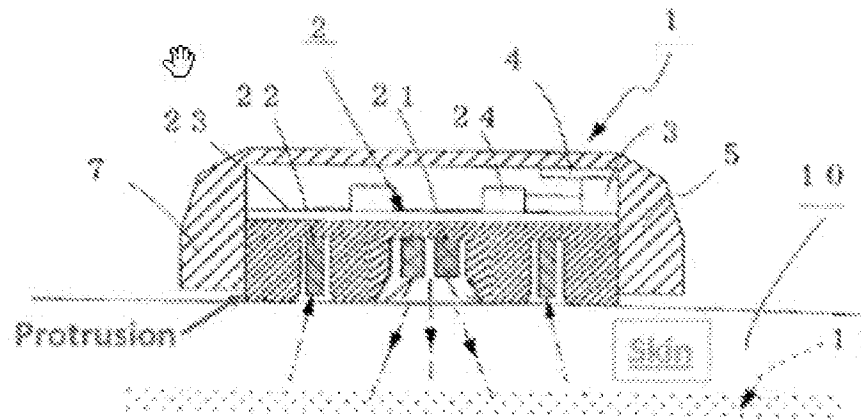
SNQ	CLAIMS	BASIS FOR REJECTION
SNQ #1A	8, 12, 20, 24, and 30	§ 103 Obviousness over Aizawa in view of Rulkov, Numaga, and Jaeb
SNQ #1B	8, 12, 20, 24, and 30	§ 103 Obviousness over Aizawa in view of Rulkov, Numaga, Jaeb, and Dalke
SNQ #2A	20, 24, and 30	§ 103 Obviousness over Al-Ali in view of Cheng, Mao, and Stivoric
SNQ #2B	8, 12, 20, 24, and 30	§ 103 Obviousness over Al-Ali in view of Cheng, Mao, Stivoric, and Rafert
SNQ #2C	30	§ 103 Obviousness over Al-Ali in view of Cheng, Mao, Stivoric, Rafert, and Matheson
SNQ #2D	8, 12, 20, 24, and 30	§ 103 Obviousness over Al-Ali in view of Cheng, Mao, Stivoric, Rafert, and Kiani, both with and without Matheson
SNQ #3A	20 and 24	§ 103 Obviousness over Hannula in view of Dorogusker
SNQ #3B	20, 24, and 30	§ 103 Obviousness over Hannula in view of Dorogusker and Matheson

Substantial New Questions of Patentability Analysis

Issue I: Requester asserts a substantial new question of patentability involving claims 8, 12, 20, 24, and 30 as being rendered obvious by Aizawa in view of Rulkov, Numaga, and Jaeb (SNQ1A) or Aizawa in view of Rulkov, Numaga, Jaeb, and Dalke (SNQ1B).

The Request presents the following proposed SNQ with respect to the claimed *protrusion comprising a convex surface*:

As discussed above in Section VIII.A.2, Aizawa's sensor includes a holder 23 that protrudes toward the user's wrist for improved adhesion and detection accuracy. See APPLE-1004 (Aizawa), [0023], [0024], [0034], FIG. 5. Indeed, as illustrated below, Aizawa's protruding holder structure includes a protrusion that is designed to be pressed against the user's skin. *Id.*; APPLE-1003 (Expert Declaration), ¶57.

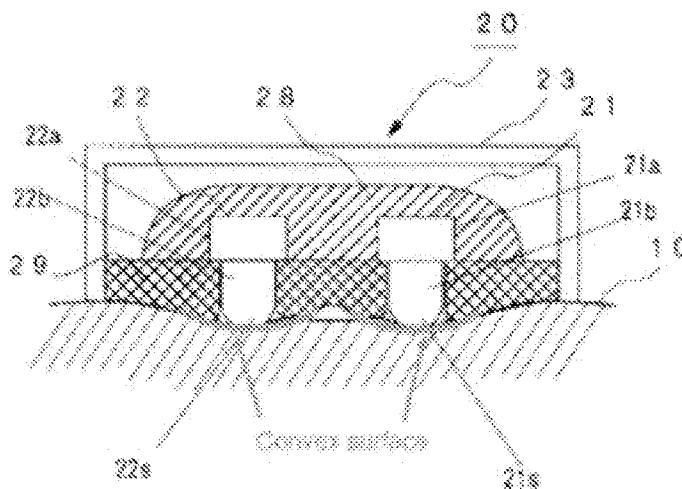


APPLE-1004 (Aizawa), FIG. 5 (annotated)

Beyond Aizawa's brief disclosure that its holder 23 can have a protrusion that is "projected from the outer casing 5" such that "adhesion can be improved," Aizawa does not provide additional details regarding the particular shape/configuration of its protrusion, for instance regarding its precise shape. APPLE-1004 (Aizawa), [0034]; APPLE-1003 (Expert Declaration), ¶58. A POSITA would have recognized, for instance, that various well-known protrusion shapes/configurations can be implemented and further that certain shapes/configurations can help enhance Aizawa's objective of improving detection efficiency. See *id.*, [0013], [0030], [0032]; APPLE-1003 (Expert Declaration), ¶58.

Along those lines, as discussed above in Section VIII.A.4, Numaga discloses an Aizawa-like holder (*i.e.*, outer support member 29) that includes a curved protrusion for improved contact with the user's wrist. See APPLE-1006 (Numaga), [0009]-[0013]; APPLE-1003 (Expert

Declaration), ¶59. As seen below, Numaga's protrusion has a convex surface that provides intimate contact with the user's skin. *Id.* Moreover, the smooth, curved shape of Numaga's protrusion helps eliminate discomfort that may be associated with a protrusion having sharp edges. APPLE-1044 (Kotanagi), [0080], [0033], [0079]; APPLE-1003 (Expert Declaration), ¶59.



APPLE-1006 (Numaga), FIG. 1(a) (annotated)

From this and related description, a POSITA would have found it obvious to implement the curved/convex protrusion of Numaga into the Aizawa-Rulkov combination device. APPLE-1003 (Expert Declaration), ¶60. In the exemplary implementation illustrated below, the flat and sharp-edged protrusion of Aizawa has been modified to incorporate the smoothly curved convex surface from Numaga's protrusion. APPLE-1003 (Expert Declaration), ¶60.

(Request 53-54)

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The Request asserts the following motivation statement for combining Numaga with Aizawa as follows:

A POSITA would have been motivated to implement a curved protrusion shape as per Numaga into Aizawa-Rulkov for various reasons. APPLE-1003 (Expert Declaration), ¶62.

First, a POSITA would have been motivated to implement a curved bottom surface because this configuration provides better physical contact and enhanced optical coupling between the sensor and the user's tissue, e.g., as compared to a flat bottom surface. APPLE-1003 (Expert Declaration), ¶63. Numaga itself recognizes such advantage, stating that "[b]ecause the light emitting surface 21s and the light receiving surface 22s are *pressed against the skin* . . . , the light path of the near-infrared light is short," and "[a]s a result, *sensor sensitivity is much higher* than when the light emitting surface 21s and the light receiving surface 22s are simply brought into contact with the wrist 10." APPLE-1006 (Numaga), [0010], [0011], [0013].

Moreover, the ability of a convex bottom surface of an optical sensor to provide good physical and optical coupling was generally recognized in the art. For example, Ohsaki explains at length that intimate contact between a convex surface and a user's skin prevents slippage of a detecting element from its position on the user, resulting in improved signal strength. APPLE-1042 (Ohsaki), [0025], FIGS. 1, 2, 4A, 4B; *see also Apple Inc. v. Masimo Corp.*, IPR2020-01537, Paper 43 at 48-62 (PTAB Feb. 23, 2022). As another example, Kotanagi explains that a wearable optical sensor with a convex user-facing surface "can be mounted in a state in which the living body surface B deforms smoothly and the contact pressure of the center part of the

(Request 56)

The Examiner respectfully disagrees that this combination would have been obvious. Requester relies on Numaga's teaching of having a raised light emitting element 21 supported by convex support member 29, and combining this with Aizawa in order to improve sensor sensitivity since the light emitting element 21 is in direct contact with a user's skin/wrist. However, the stated benefit of this structural configuration is destroyed when combined with Aizawa, since Requester's proposed combination (See Request, composite figures at 55-56)

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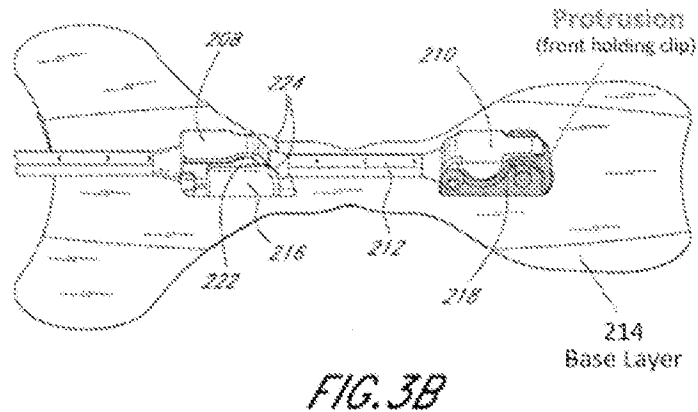
utilizes Numaga's convex support member with the recessed light emitter of Aizawa, which is recessed within/inside the support member. This combination would contradict and disparage the teachings of Numaga which makes it clear that the advantages of improved sensor sensitivity are obtained by placing the light emitting element 21 in direct contact with the user's skin (See Numaga ¶ 7, 10, and 11). Without the raised lighting element 21 that comes in contact with the user's skin, there would be no need for Numaga's convex support member. Therefore, one of ordinary skill in the art would not be motivated to utilize Numaga's convex support member in the combination and structural configuration proposed by the Request.

Furthermore, the proposed combination relies on Jaeb for teaching the claimed feature of a window extending across each of the openings (Request, 58-60). However, Numaga states that "...because there is no transparent panel such as an acrylic panel, no ambient light scattered by the transparent panel reaches the light receiving element, and this improves pulse wave detection (See Numaga ¶ 7). Thus, placing a window over Numaga's light emitting element would further disparage the Numaga reference.

Accordingly, a reasonable examiner would not consider evaluation of the Numaga reference, as presented in the proposed combination, as being important in determining the patentability of the claims since the proposed combination fails to teach or suggest the allowable features identified during prosecution. Accordingly, SNQ1A and SNQ1B **do not** raise a substantial new question of patentability.

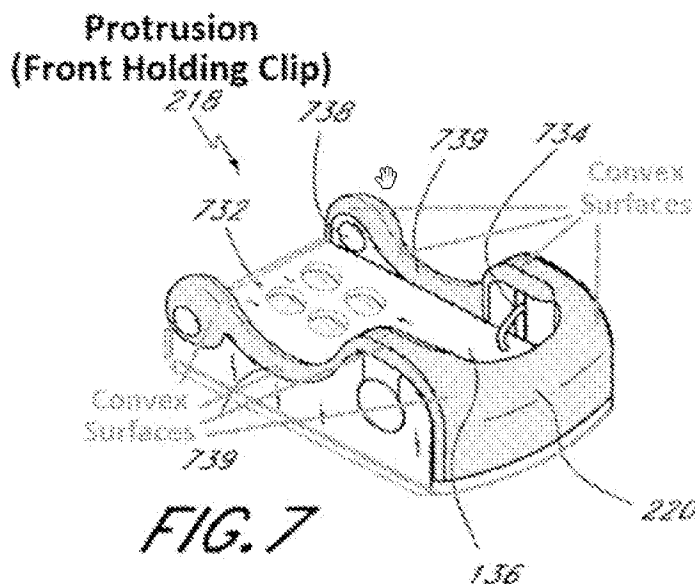
Issue II: Requester asserts a substantial new question of patentability involving claims 20, 24, and 30 as being rendered obvious by Al-Ali, Cheng, Mao, and Stivoric (SNQ2A).

The Request relies on the teachings of Al-Ali with respect to the claimed *protrusion comprising a convex surface*, mapping the front holding clip 218 as being the claimed *protrusion*, and relying on the holding clip edges (rounded side walls 739 and front stop 220) as being the claimed *convex surface* of the protrusion:



Excerpt from APPLE-1010 (Al-Ali), FIG. 3B (annotated)

(See Request, p. 121, Al-Ali, Fig. 3B, as annotated by Requester)



(See Request, p. 123, Al-Ali, Fig. 7, as annotated by Requester)

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Assuming that that the front holding clip 218 is the claimed protrusion, as proposed in the request, the Examiner disagrees that the *surface* of front holding clip 218 is convex. While the edges of the front holding clip 218 has raised edges/side walls 739 and 220, they do not create a convex surface, but instead form a flat surface that envelops a user's finger.

Turning to the specification of the '648 patent, the following context is found regarding the claimed *protrusion comprising a convex surface*.

In an embodiment, a physiological sensor includes a **detector housing** that can be coupled to a measurement site, such as a patient's finger. The sensor housing can include **a curved bed** that can generally conform to the shape of the measurement site. In addition, the **curved bed can include a protrusion** shaped to increase an amount of light radiation from the measurement site.

(the '648 patent, Col. 7: 48-54)

Referring to FIG. 3A, the sensor 301a in the depicted embodiment is a clothespin-shaped clip sensor that includes an **enclosure 302a for receiving a patient's finger**. The **enclosure 302a is formed by an upper section or emitter shell 304a**, which is pivotably connected with **a lower section or detector shell 306a**. The emitter shell 304a can be biased with the detector shell 306a to close together around a pivot point 303a and thereby sandwich finger tissue between the emitter and detector shells 304a, 306a.

(the '648 patent, Col. 18: 37-45)

Referring to FIGS. 3B and 3C, an example of **finger bed 310** is shown in the sensor 301b. The finger bed 310 **includes a generally curved surface shaped generally to receive tissue**, such as a human digit. **The finger bed 310 includes one or more ridges or channels 314. Each of the ridges 314 has a generally convex shape** that can facilitate increasing traction or gripping of the patient's finger to the finger bed. Advantageously, the ridges 314 can improve the accuracy of spectroscopic analysis in certain embodiments by reducing noise that can result from a measurement site moving or shaking loose inside of the sensor 301a. The ridges 314 can be made from reflective or opaque materials in some embodiments to further increase SNR. In other implementations, other surface shapes can be used, such as, for example, generally flat, concave, or convex finger beds 310.

(the '648 patent, Col. 19: 7-21)

The example of finger bed 310f shown also includes the protrusion 605b, which includes the features of the protrusion 605 described above. In addition, the **protrusion 605b also**

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includes chamfered edges 607 on each end to provide a more comfortable surface for a finger to slide across (see also FIG. 14D). In another embodiment, **the protrusion 605b could instead include a single chamfered edge 607 proximal to the ridges 314.** In another embodiment, one or both of the chamfered edges 607 could be rounded.

(the '648 patent, Col. 25: 63 – col. 26: 4)

The '648 patent makes a clear distinction between the detector housing/enclosure/emitter shell/detector shell, vs. the finger bed which includes the protrusion having a *convex surface*. Thus, given the broadest reasonable interpretation in light of the '648 specification, it would be an unreasonable interpretation to map the claimed *protrusion comprising a convex surface* as being the housing/side walls 379 of the holding clip 218 since this structure is more reasonably mapped to the housing/shell/enclosure of the '648 patent terminology. Al-Ali teaches a front holding clip 218 that has a *flat finger bed surface*, not a protrusion having a convex surface.

Moreover, Requester's proposed SNQ2B, SNQ2C, and SNQ2D below relies on an inconsistent mapping of Al-Ali, where the front holding clip 218 is no longer relied upon as being the claimed *protrusion* and, and no longer relies on the holding clip edges (rounded side walls 739 and front stop 220) as being the claimed *convex surface* of the protrusion. Instead, Al-Ali's finger bed is proposed as being modified by Rafert to teach a protrusion with a convex surface. (See Request, p. 173 and 196). Why would there be a need to modify Al-Ali, with a protrusion having a convex surface if Al-Ali allegedly already has this structure? This inconsistency in mapping further illustrates the unreasonable claim interpretation applied in the proposed SNQ2A.

Therefore, a reasonable examiner would not consider evaluation of the Al-Ali reference, as presented in the proposed combination, as being important in determining the patentability of the claims, since the proposed combination fails to teach or suggest the allowable features

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identified during prosecution. Accordingly, SNQ2A **does not** raise a substantial new question of patentability.

Issue III: Requester asserts a substantial new question of patentability involving claims 8, 12, 20, 24, and 30 as being rendered obvious by Al-Ali, Cheng, Mao, Stivorc, and Rafert (SNQ2B); claim 30 as being rendered obvious by Al-Ali, Cheng, Mao, Stivorc, Rafert, and Matheson (SNQ2C); claims 8,12, 20, 24, and 30 as being rendered obvious by Al-Ali, Cheng, Mao, Stivorc, Rafert, Kiani, with and without Matheson (SNQ2D).

The Request relies on the teachings of *Rafert* with respect to the claimed *protrusion comprising a convex surface*:

As discussed in Section VIII.D.3 and [8d] above, the Al-Ali-Cheng-Mao-Stivorc-Rafert combination includes a protrusion comprising a convex surface. APPLE-1003 (Expert Declaration), ¶333. In particular, based on Rafert, it would have been obvious to include a protrusion with a convex surface over the photodiodes, at the region of contact where light is received from user tissue. *Id.* This protrusion with a convex surface would have been obvious because, as Rafert teaches, the pressure applied by the protrusion “*provides improved accuracy and sensitivity in arterial oxygen saturation measurement*, especially in circumstances of low perfusion.” APPLE-1014 (Rafert), Abstract (emphasis added). The convex surface would be located over the photodiodes and would project toward and apply localized stress to the user tissue measured using the photodiodes, as Rafert teaches, which would decrease the amount of venous blood measured and increase the accuracy of arterial blood oxygen saturation levels. *Id.*, 4:13-58. A POSITA would also have been motivated to apply pressure with the convex surface to “minimize any shearing effects when applied to a patient’s skin” and to create a “smooth boundary transition” that improves signal quality and comfort. *Id.*, 5:25-33.

(Request p. 196, see also, p. 173-177)

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Requester's stated motivation for modifying Al-Ali's finger bed with the protrusion having a convex surface based on Rafert's teaching is improper. First, Requester's proposed SNQ2A already alleges that Al-Ali has the claimed structure of a *protrusion comprising a convex surface*. Thus, why would there be a need to modify Al-Ali with Rafert with this inconsistent mapping and modification of Al-Ali? Secondly, the motivation statement relied upon comes from Rafert's teaching:

When the sensor is conformably applied to the patient's body portion, **localized pressure is exerted on the body portion at the points of contact with the light source and light detector assemblies**, thereby stressing the skin and the underlying blood-perfused tissue. **The stress imparted to the skin** and underlying tissues affects the distributions of blood in the tissues and **provides improved accuracy and sensitivity** in arterial oxygen saturation measurement, especially in circumstances of low perfusion.

(Rafert, Abstract)

Rafert thus achieves improved accuracy/sensitivity by placing the light source/detector in direct contact with a user's skin, not by merely providing a protrusion with a convex surface.

Requester's proposed composite combination does not appear to protrude the light elements to contact the user's skin to gain the benefits of the motivation statement which is relied upon.

Furthermore, Requester's proposed modification destroys the teachings of Al-Ali and Rafert even if Rafert's LEDs were to be proposed as protruding through Al-Ali's finger bed. Protruding the lights of Rafert and integrating the light source/detector through the finger bed hole of Al-Ali's front holding clip 218 would disparage the teachings of Al-Ali's disposable component.

Al-Ali teaches:

[0049] FIG. 2 also shows the **disposable component 206 including a base 214, an assembly/disassembly clip 216 and a front holding clip 218**, the clips each adapted to accept the emitter casing 208 and detector casing 210, respectively. In the preferred embodiment, front holding clip 218 includes a front stop 220. Front stop 220 is advantageous for a number of reasons. It helps reduce the likelihood that the reusable component 102, and in particular detector casing 210, will slide forward in the front holding clip 218 during assembly or use. In addition, in an embodiment where the stop

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220 comprises rubber or other liquid resistant material, the stop 220 provides a liquid resistant connection between the detector casing 210 and front holding clip 218, reducing the likelihood of sensor contamination and electrical shorts. Rubber or a similar material may be used in an embodiment to compose such a front stop 220.

(Al-Ali, 49)

[0055] FIG. 7 shows a close up perspective view of an embodiment of the front holding clip 218, again to show detail less easily seen in smaller figures. While most of the front sensor clip 218 may be made of plastic or some other rigid material, the preferred embodiment has front stop 220 made of rubber as has been discussed. Opening 732 is also shown here and may be a hole through front holding clip 218 or may just be of a generally transparent material that will allow light from the LEDs to enter the tissue at the measurement site and allow light energy to be read by the photodiode. **Having window 732 be transparent material will allow the sensor to obtain readings while keeping the LEDs and photodiode from becoming contaminated.** Other optical filters or the like could also be housed in window 732.

(Al-Ali, 55)

Integrating the electronic components, such as the light emitting diodes (LEDs) of Rafert into the disposable front holding clip 218 of Al-Ali, destroys the teaching of Al-Ali's goal of keeping holding clip 218 as a separate *disposable* component. Additionally, protruding the LEDs of Rafert through Al-Ali's finger bed further teaches away from Al-Ali's teaching of keeping the LEDs and photodiodes from being contaminated.

Therefore, a reasonable examiner would not consider evaluation of the Rafert reference, as presented in the proposed combination, as being important in determining the patentability of the claims since the proposed combination fails to teach or suggest the allowable features identified during prosecution. Accordingly, SNQ2B, SNQ2C, and SNQ2D **do not** raise a substantial new question of patentability.

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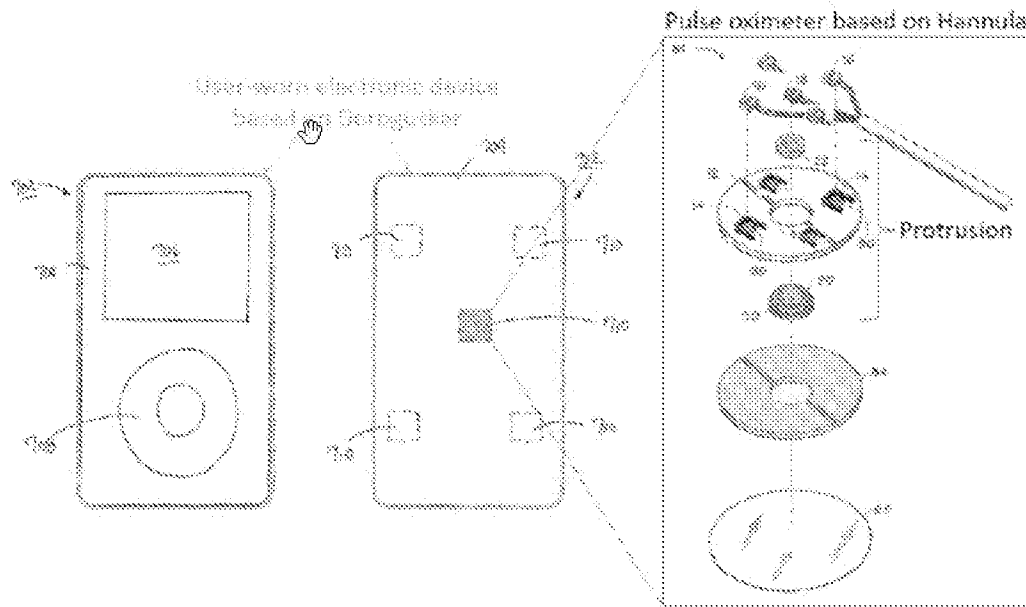
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Issue IV: Requester asserts a substantial new question of patentability involving claims 20 and 24 as being rendered obvious by Hannula and Dorogusker (SNQ3A); claims 20, 24, and 30 as being rendered obvious over Hannula, Dorogusker, and Matheson (SNQ3B).

The request first proposes modifying Hannula's single LED 18 to provide the claimed "plurality of LEDs" (Request, 267-269), and further modifying Hannula's two light detectors 16 by providing the claimed "at least four photodiodes" (Request, 270-275). A question arises as to whether one of ordinary skill in the art would have found it obvious to reconstruct this particular claimed configuration based on Hannula without hindsight.

Next the request addresses the claimed "protrusion comprising a convex surface and a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes" as follows:

In the Hannula-Dorogusker combination electronic device, the pulse oximetry sensor is integrated onto the back face of the electronic device, as illustrated in the figure *infra*. See APPLE-1017 (Dorogusker), [0066] "one or more sensors 710 can be disposed to interact with the user from a back face of the electronic device"); APPLE-1003 (Expert Declaration), ¶504. In this configuration, elements of the pulse oximetry sensor constitute a **protrusion**. APPLE-1003 (Expert Declaration), ¶504.



Hannula-Dorogusker composite figure

barrier of the pulse oximetry sensor as a single, integral element in light of Hannula's own disclosure that "[t]he components of the sensor assembly 10 may be modular, one piece, and/or custom built according to operational requirements." APPLE-1015 (Hannula), 4:2-4; APPLE-1016 (Hannula Prov.), [0028]; APPLE-1003 (Expert Declaration), ¶507. In this implementation, the single, integral element that includes the substrate, light pipe, and optical barrier is a **protrusion**, for at least similar reasons as those for which the combination of the substrate, light pipe, and optical barrier as discrete elements are together a protrusion. APPLE-1003 (Expert Declaration), ¶507.

(Request, 275-277)

Thus, the Request maps Hannula's pulse oximeter sensor 81, as a whole) as being the claimed protrusion, then proceeds to point to Hannula's light pipe 22, substrate 12, and optical barrier 20 as together forming a *protrusion*.

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It is first noted that this mapping is inconsistent and therefore unreasonable. If sensor 81 as a whole is considered to be the claimed protrusion, it is not a protrusion until it is modified, as proposed in the request, to be attached to the back face of the electronic device of the Dorogusker reference (See Requester's composite drawing p. 276). Thus, Requester's proposed modification is creating the claimed *protrusion* feature, rather than the reference itself teaching the claimed *protrusion* structure.

Next, the request points to light pipe 23 and bottom surface 71 for teaching "the protrusion includes a convex surface" (Request, 278-279).

This mapping is again inconsistent, since the light pipe 23 is now being relied upon as the protrusion comprising a convex surface 71, rather than the entire sensor 81 which was previously relied upon as protruding from the Dorogusker device. Assuming light pipe 23 is the claimed *protrusion comprising a convex surface*, this mapping fails to show the protrusion comprising a convex surface and a *plurality of through holes*, each through hole including a window and arranged over a different one of the at least four photodiodes.

The protrusion created by light pipe 23 comprises a convex surface 71, however this protrusion/convex surface has a *single* through hole and does not comprise a plurality of through holes. Next, in order to meet the limitation that the *protrusion* includes a *plurality of through holes*, the request reassigns the claimed *protrusion* such that the bottom portion sensor substrate 12 is the protrusion so that openings 90 can be relied upon as the through holes. (See composite drawing Request, 281). The bottom portion of sensor substrate 12 however does not have a convex surface. Hannula indicates that "...the bottom portion of the sensor substrate 12 may be roughened or textured to better facilitate a uniform scattering of the light through the adhesive". At best, Hannula teaches a device having sensor substrate 12 comprising a flat surface that may

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be textured, and having openings capable of securing optical components such as light pipe 22/23 which has a convex surface on the light pipe (See Hannula, Col. 5, 35-43).

Turning now to FIG. 2, a top view of the sensor substrate 12 in accordance with an embodiment is illustrated. In an embodiment the sensor substrate 12 comprises an outer portion 40 and a central opening 42. *The central opening 42 may be capable of securing the optical barrier 20 and the light pipe 22 adjacent the sensor assembly 10 and 11.* The outer portion 40 of the sensor substrate 12 may be capable of supporting optical slots 14, designated for securing the optical components, such as detectors 16 or emitter 18.

Thus, Hannula fails to meet the limitation, “a *protrusion* comprising a *convex surface* and a *plurality of through holes*, each through hole including a window and arranged over a different one of the at least for photodiodes.”

The Request improperly relies on Hannula’s pulse oximeter sensor 81 as being the claimed protrusion, then proceeds to point to Hannula’s separate components - light pipe 22, substrate 12, and optical barrier 20 as together forming a *protrusion*, and also points to the light pipe 22 as being the protrusion having the convex surface. This mapping of separate components of Hannula as being the claimed *protrusion comprising a convex surface and a plurality of through holes*, is inconsistent and therefore unreasonable.

Accordingly, a reasonable examiner would not consider evaluation of the Hannula reference, as presented in the proposed combination, as being important in determining the patentability of the claims since the proposed combination fails to teach or suggest the allowable features identified during prosecution. Accordingly, SNQ3A and SNQ3B **do not** raise a substantial new question of patentability.

35 U.S.C. § 325 (d)

On April 12, 2024, Patent Owner filed a combined petition Under 37 C.F.R. §§ 1.183 and 1.182 to deny this instant *ex parte* Reexamination Request Under 35 U.S.C. § 325(d). On April 26, 2024, Third Party Requester filed an Opposition to Patent Owner’s April 12, 2024 petition.

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On May 3, 2024, the Office issued a decision which granted Patent Owner's April 12, 2024 1.183 petition to waive the rules to the extent necessary to permit entry and consideration of Patent Owner's 325(d) arguments in the April 12, 2024 petition by the Examiner in making a determination on the Request for reexamination of the '648 patent. Since, the Request for reexamination has been denied on the merits for the reasons set forth above, Patent Owner's arguments relating to a discretionary denial of reexamination pursuant to 35 USC 325(d) are moot and will not be addressed.

Conclusion

Claims 8, 12, 20, 24, and 30 will not be reexamined.

All correspondence relating to this *ex parte* reexamination proceeding should be directed:

By Patent Center: To file and manage patent submissions in Patent Center, visit:
<https://patentcenter.uspto.gov>.
Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format.

By mail to: Attn: Mail Stop "Ex Parte Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand: Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314.

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Any inquiry concerning this communication or earlier communications from the examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

/Cameron Saadat/
Patent Reexamination Specialist, Art Unit 3992

Conferees:
/Karin Reichle/
Primary Examiner, Art Unit 3992

/ALEXANDER J KOSOWSKI/
Supervisory Patent Examiner, Art Unit 3992

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN WEARABLE ELECTRONIC
DEVICES WITH ECG FUNCTIONALITY
AND COMPONENTS THEREOF**

Inv. No. 337-TA-1266

**RESPONDENT APPLE INC.'S EMERGENCY MOTION TO SUSPEND ANY
REMEDY OR EXTEND THE TARGET DATE AND STAY PROCEEDINGS
PENDING RESOLUTION OF ANY APPEAL OF THE PATENT OFFICE'S DECISION
THAT UNITED STATES PATENT NOS. 10,638,941, 10,595,731, AND 9,572,499 ARE
UNPATENTABLE.**

INTRODUCTION

On December 6, 2022, the Patent Trial and Appeal Board (“PTAB”) issued Final Written Decisions holding unpatentable all asserted claims of the three patents at issue in this Investigation: United States Patent Nos. 10,638,941 (“the ’941 patent”), 10,595,731 (“the ’731 patent”), and 9,572,499 (“the ’499 patent”). The PTAB’s Final Written Decisions are appended to this Motion.

In light of the PTAB’s recent orders, Respondent Apple Inc. (“Apple”) respectfully petitions the Commission to suspend any remedial orders or, in the alternative, extend the December 12, 2022 Target Date of its Final Determination and stay all proceedings prior to issuance of any Final Determination pending final resolution of any appeal of the PTAB’s decisions. A suspension is consistent with the Commission’s routine past practice. A stay will simplify the issues and conserve agency and party resources—by avoiding issuance of a merits determination that is likely to be mooted by an affirmation of the PTAB’s Final Written Decisions—without causing any harm to Complainant. And either a suspension or a stay accords due deference to the Patent Office’s role as the lead agency in assessing patentability and honors Congress’s intent that invalid patents should not be enforced.

Given the short time until the Commission’s December 12, 2022 Target Date, Apple asks that the Commission consider this Motion on an emergency basis.¹

FACTS

This Investigation concerns three heart-health monitoring features of Apple Watch: the ECG app, Irregular Rhythm Notification (“IRN”), and High Heart Rate Notification (“HHRN”). The ECG app enables users to take electrocardiograms to determine whether they are experiencing atrial fibrillation (“AFib”), a potentially life-threatening heart condition that afflicts millions in the United States. IRN monitors the regularity of users’ heart rates to identify signs consistent with AFib. HHRN informs users

¹ Counsel for Apple contacted counsel for Complainant and for the Office of Unfair Import Investigations (“OUII”) regarding this Motion. Complainant has not yet indicated its position on this Motion and will provide its position after it sees the Motion. Counsel for OUII support the motion to the extent that it asks the Commission to suspend enforcement of any remedial orders pending appeal of the PTAB’s Final Written Decisions, but otherwise oppose the Motion. The Commission may wish to extend the Target Date for a Final Determination to allow sufficient time for full briefing and consideration of this Motion.

when their heart rates are elevated above a user-set threshold during periods of relative inactivity.

Complainant AliveCor, Inc. (“AliveCor”) filed a § 337 Complaint against Apple, alleging that Apple Watches with these heart-health features infringe certain claims of three of its patents: the ’941 patent, the ’731 patent, and the ’499 patent. The Commission thereafter instituted this Investigation. In June 2022, an Administrative Law Judge issued an Initial Determination finding § 337 violations with respect to the ’941 and ’731 patents and no violation with respect to the ’499 patent. The Initial Determination recommended issuing a limited exclusion order and cease and desist order barring Apple from importing and selling the accused Apple Watches. The Commission determined to review the Initial Determination in part and requested submissions from the parties regarding certain merits questions as well as the issues of remedy, the public interest, and bonding.

In its submissions to the Commission, Apple explained that it had filed *inter partes* review (“IPR”) petitions on the three patents with the PTAB, EDIS No. 745156, and that the PTAB had instituted IPRs for all asserted claims, EDIS No. 759993, Ex. A, at 48, Ex. B at 47, and Ex. C at 53. Apple also stated that Final Written Decisions on those claims were expected before the Commission’s Target Date in this Investigation. Accordingly, Apple suggested that the Commission suspend any remedial orders pending resolution of the PTAB’s Final Written Decisions. *See* Respondent’s Initial Submission, EDIS No. 782052, at 69-70; *see also* Respondent’s Reply Submission, EDIS No. 782552, at 44-45. Both Staff and AliveCor argued in their submissions that a suspension was unwarranted because the PTAB had not yet found any asserted claim unpatentable. *See* Staff’s Reply Submission, EDIS No. 782587, at 20-21; Complainant’s Reply Submission, EDIS No. 781827, at 38-39. Staff, however, agreed that “it may be appropriate to delay the effect of any remedial orders” “[s]hould ... the PTAB issue a Final Written Decision that affects the asserted claims prior to the Commission’s final determination on violation.” Staff’s Reply Submission, EDIS No. 782587, at 21.

As Apple anticipated, the PTAB has now issued its Final Written Decisions and has determined that the claims of the three patents asserted in this Investigation are unpatentable because they are obvious

be cancelled, and there will be no violation of § 337 predicated on those claims. *See* 35 U.S.C. § 318(b). And “regardless of the final outcome” of the PTAB’s Final Written Decisions on appeal, the Commission would “benefit in being able to consider” the Federal Circuit’s reasoning. *Semiconductor Chips*, 2008 WL 2223426, at *2-3. The Commission has determined to review the ID’s invalidity determinations, EDIS No. 780874 at 2, and therefore would benefit from any guidance on the invalidity issues that the Federal Circuit provides. A stay will not unduly prejudice or disadvantage AliveCor because it discontinued the only product that purportedly practiced the asserted claims, and its purported new products have never materialized. ID at 167. Nor are AliveCor’s patents at risk of expiring before the stay would be lifted. *Contra Semiconductor Chips*, 2008 WL 2223426, at *4. The ’941 patent expires in 2036, and the ’731 and ’499 patents expire in 2034. *See* EDIS No. 740951 at 14-16. The stage of the PTAB’s proceedings also weighs heavily in favor of a stay; the PTAB has issued Final Written Decisions as to all asserted claims. And a stay will conserve Commission resources because it will not need to render a Final Determination if the PTAB rulings are affirmed or not challenged. Nor will the Commission need to expend resources defending an appeal that ultimately could be mooted by the cancellation of the claims. A stay will also preserve governmental resources, including avoiding any burden on the U.S. Trade Representative and U.S. Customs and Border Protection. Only one factor—the stage of the Commission proceedings—arguably weighs against a stay. But this is just one factor among five, and the PTAB has completed its review whereas the Commission has not.

An extension of the Target Date until the conclusion of any review of the PTAB’s decision and accompanying stay of the Investigation prior to issuance of any Final Determination on the merits is warranted. Additionally, as discussed below, an extension and stay is fully consistent with Congressional intent.

III. A Suspension Of Any Remedial Orders Or Stay Of These Proceedings Is Consistent With Congressional Intent.

Where, as here, the PTAB issues a Final Written Decision of unpatentability a suspension of any remedy or a stay of these proceedings and extension of the Target Date faithfully implements several Congressional directives.

First, a suspension or stay “recognizes the [Patent Office’s] role as the lead agency in assessing patentability, or validity, of proposed or issued claims” by ensuring that the Commission does not contradict the PTAB’s unpatentability determinations. *Unmanned Aerial Vehicles*, 2020 WL 5407477, at *21 (citing *Fresenius USA, Inc. v. Baxter Int’l Inc.*, 721 F.3d 1330, 1339, 1334 (Fed. Cir. 2013)); *see also Magnetic Tape Cartridges*, 2019 WL 2635509, at *38 n.23; *Three-Dimensional Cinema*, 2016 WL 7635412, at *37. Congress and the courts have long recognized that the Patent Office is the lead federal agency for determining patentability. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988). Congress has further emphasized the Patent Office’s leadership and expertise on matters of patentability when it established the PTAB as part of the America Invents Act. *See* S. Rep. No. 110-259, at 5, 23 (2008); 35 U.S.C. §§ 6(a), (b)(4). In contrast, Congress has made clear that § 337 is a “trade statute,” not a patent statute. *Suprema, Inc. v. Int’l Trade Comm’n*, 796 F.3d 1338, 1344-45 (Fed. Cir. 2015) (en banc). Unlike the PTAB, which can formally cancel a patent claim after its unpatentability decision has been finally resolved, *see* 35 U.S.C. § 318(b), the Commission’s determinations on patent validity “are for purposes of adjudicating whether or not a Section 337 violation has occurred, and are not binding on the [Patent Office], federal courts, or other tribunals, even if affirmed by the Federal Circuit,” *Unmanned Aerial Vehicles*, 2020 WL 5407477, at *21 (citing *Hyosung TNS Inc. v. Int’l Trade Comm’n*, 926 F.3d 1353, 1358 (Fed. Cir. 2019)); *see Tex. Instr. Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1568-69 (Fed. Cir. 1996) (“The Commission’s findings neither purport to be, nor can they be, regarded as binding interpretations of the U.S. patent laws in particular factual contexts.” (quoting S. Rep. No. 93-1298, at 196 (1974))). The Patent Office recently emphasized these differences between the two agencies in explaining why it “no longer discretionarily denies petitions based on ... parallel ITC proceeding[s].” *Interim Procedures for Discretionary Denials*, U.S. Patent & Trade Office (June 21, 2022), <https://tinyurl.com/mwvyajej>.

Second, a suspension or stay would “give[] effect to the Congressional goal” regarding the IPR procedure under the America Invents Act. *Unmanned Aerial Vehicles*, 2020 WL 5407477, at *21. Congress intended IPRs to “provide ‘a quick, inexpensive, and reliable alternative to district court litigation to resolve questions of patent validity.’” *Id.* (quoting S. Rep. No. 110-259, at 20); *see also SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1352 (2018) (explaining that IPRs “allow[] private parties to challenge previously issued patent

claims in an adversarial process before the Patent Office that mimics civil litigation”). “Because Congress intended [IPRs] be an alternative to district court litigation, and because the Commission does not issue enforceable remedial relief for claims held invalid by a district court, ... suspending enforcement of remedial orders is appropriate for patent claims determined to be unpatentable by a final written decision of the PTAB issued prior to the Commission’s final determination.” *Magnetic Tape Cartridges*, 2019 WL 2635509, at *38 n.23 (quoting 19 U.S.C. § 1337(b)(1)); *see also Unmanned Aerial Vehicles*, 2020 WL 5407477, at *21.

District courts likewise adhere to this Congressional preference by staying their proceedings when the PTAB issues an unpatentability decision before entry of a final court judgment. *See, e.g., Ultratec, Inc. v. Sorenson Commc’ns, Inc.*, No. 13-cv-346-bbc, 2015 WL 2248437, at *1, *6 (W.D. Wis. May 13, 2015) (finding PTAB’s unpatentability decision warranted stay despite the “very late stage of litigation” because affirmance of the PTAB’s decision would moot plaintiffs’ infringement claims), *mandamus denied and appeal dismissed*, 611 F. App’x 720, 721-23 (Fed. Cir. 2015); *Prisua Eng’g Corp. v. Samsung Elecs. Co.*, 472 F. Supp. 3d 1183, 1186 (S.D. Fla. 2020) (similar). Indeed, the Commission has stated that it “is unaware of any case in which a district court has entered an injunction (or awarded damages) over a PTAB final written decision of unpatentability, even when the PTAB issues its final decision after trial but prior to the entry of final judgment.” Br. of Appellee, *Autel Robotics*, 2021 WL 2791360, at *33-34.

Third, “[t]he Commission may issue an exclusion order in a patent-based investigation only if it finds that the accused articles ‘infringe a *valid* and enforceable United States patent.’” *Unmanned Aerial Vehicles*, 2020 WL 5407477, at *20 (emphasis in original) (quoting 19 U.S.C. § 1337(a)(1)(B)(i), (d)(1)); *see also Vision-Based Driver Assistance System Cameras*, Inv. No. 337-TA-907, Comm’n Op., 2015 WL 13817121, at *22 (Dec. 1, 2015) (holding that an “invalid” claim cannot establish a domestic industry). If the PTAB’s Final Written Decisions are affirmed on appeal (or not appealed), the PTAB will “cancel[]” each of the asserted claims it found to be unpatentable. *See* 35 U.S.C. § 318(b). An affirmance is likely: In appeals from IPRs, the Federal Circuit has affirmed the PTAB in full or in part over 83% of the time through April 2022. *See* Daniel F. Klodowski & Audrey J. Parker, *Federal Circuit PTAB Appeal Statistics Through April 30, 2022*, Finnegan (May 31, 2022), <https://tinyurl.com/cn3cywtp>. Thus, a suspension or stay is necessary to

Exhibit C

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

ALIVECOR, INC.,
Patent Owner.

IPR2021-00970
Patent 9,572,499 B2

Before ROBERT A. POLLOCK, ERIC C. JESCHKE, and
DAVID COTTA, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Denying In-Part and Dismissing In-Part as Moot
Patent Owner's Motion to Exclude Evidence
37 C.F.R. § 42.64

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ENTIRELY REDACTED

APPX71228-71231
ENTIRELY REDACTED

APPX71232-71233
ENTIRELY REDACTED

APPX71234-71235
ENTIRELY REDACTED

APPX71236-71240
ENTIRELY REDACTED

APPX71241-71244
ENTIRELY REDACTED

4/10/24, 3:01 PM

Apple Steps Up Its Lobbying to Change Patent Rules - The New York Times

The New York Times<https://www.nytimes.com/2024/03/19/technology/apple-patents-lobbying.html>

Apple Keeps Losing Patent Cases. Its Solution: Rewrite the Rules.

After losing two complaints before the U.S. International Trade Commission, Apple has stepped up its lobbying to change the agency's practices.

**By Tripp Mickle**

Tripp Mickle has covered Apple since 2016.

March 19, 2024

Over the past decade, some of Apple's biggest regulatory headaches have come from a little-known federal agency called the U.S. International Trade Commission. The agency's patent judges have found Apple guilty of appropriating innovations in smartphones, semiconductors and smartwatches. And recently, they forced Apple to remove a health feature from Apple Watches.

Now the tech giant is pushing back. While it defends itself from patent complaints before the I.T.C., Apple has begun lobbying lawmakers to help rewrite the agency's rules.

The company has been campaigning across Washington for legislation that would make some patent owners ineligible to bring complaints before the I.T.C. It has sought to influence the language of committee reports that could affect how the agency levels punishments. And it has added to its lobbying might by enlisting one of the agency's former commissioners.

The lobbying effort comes as Apple is enmeshed in a multiyear legal battle with two U.S. medical device makers over technology in the Apple Watch. The companies, AliveCor and Masimo, filed complaints in the I.T.C. against Apple in 2021 for appropriating innovations they had developed to measure the heart's electrical activity and people's blood oxygen levels.

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Apple Steps Up Its Lobbying to Change Patent Rules - The New York Times

After losing both cases, Apple this year removed the technology to measure blood oxygen in its watches, which infringed on Masimo's patent. It is appealing the I.T.C.'s decision. A similar punishment is on hold as court proceedings continue related to the I.T.C.'s finding that Apple infringed on AliveCor's innovations with the Apple Watch's electrocardiogram feature.

Apple is trying to blunt the agency's signature power. Unlike traditional patent courts, where juries or judges typically issue fines, the I.T.C.'s judges can discipline a company that violates a patent by banning imports of the infringing product.

Because Apple makes all its signature devices overseas, a block on the import of its devices would be perilous to the company. To avoid that penalty in the future, the company says, it wants the agency to put the public interest of a product ahead of a ban. The company is betting that the court would then give more credence to Apple's argument that Americans would be harmed by an import ban because they would lose access to the communication and health features in iPhones and Apple Watches.

An Apple spokeswoman said the existing law requires that the I.T.C. consider how the public interest could be affected before ordering an import ban. But it said public data showed that the agency had made public-interest evaluations in only one-fifth of cases it had heard since 2010. As a result, its lobbyists have been talking with White House and congressional leaders about the I.T.C., as well as other issues such as privacy and domestic manufacturing.

Adam Mossoff, a patent law expert and a professor at George Mason University, said Apple was misinterpreting the law, which requires the I.T.C. to block a product if it finds that it infringes on a patent. An import ban is supposed to be overruled only if there's a proven threat to health or safety, he said. Blocking sales of an Apple device wouldn't qualify as harmful.

"The problem with their lobbying is that they're trying to neuter a well-functioning court by closing its doors to Americans who have had their rights infringed," he said.

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Apple Steps Up Its Lobbying to Change Patent Rules - The New York Times

When Congress set up what became the I.T.C. in 1916, it wanted to protect American innovation by allowing the U.S. government to ban the import of products with stolen technology. But as manufacturing moved overseas, the federal agency's court system became a forum for disputes between U.S. companies.

The I.T.C.'s judges, who are appointed by the commission, hold hearings with different standards for patent disputes than those that govern District Court cases. The cases are fast and compressed and can culminate with the judge's punishing a patent abuser by blocking its products.

Before a ban is put into effect, a company that's found guilty can appeal to the White House for a reprieve. But it's rare for an administration, which oversees the agency, to go against a judge's recommendation.

Apple has become the pre-eminent example of how the I.T.C. can be used. Because the company manufactures almost all its products overseas, the judges who have found it guilty of infringing on patents in smartphones, semiconductors and smartwatches say it should be punished by blocking the import of iPhones, iPads and Apple Watches.

Apple has largely escaped the import bans. In 2013, the Obama administration vetoed the I.T.C.'s plan to block iPhone imports after the agency determined that Apple had infringed on one of Samsung's smartphone patents. In 2019, Apple agreed to pay Qualcomm a royalty for some wireless technology patents, heading off an I.T.C. ruling that could have blocked iPhone sales. And after losing the Masimo case, Apple agreed to remove the infringing health feature to dodge an Apple Watch ban.

For years, Apple avoided the kind of lobbying that was customary for a large corporation. It kept a small office in Washington staffed by just a few people and employed only one lobbying firm, two people familiar with the company's practices said. But as regulatory challenges to its business have risen, its policy team has swelled to include dozens of people and 11 lobbying firms.

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Apple Steps Up Its Lobbying to Change Patent Rules - The New York Times

In the face of the patent complaints from AliveCor and Masimo, Apple's team in Washington gave priority to lobbying to change the I.T.C. In 2022, it began working with the ITC Modernization Alliance, a loose-knit coalition of companies that includes Samsung, Intel, Dell, Google, Verizon and Comcast. The group worked with members of Congress as it wrote the Advancing America's Interest Act in 2019 and supported its reintroduction in 2023.

The bill's backers — Representatives David Schweikert, a Republican from Arizona, and Donald S. Beyer Jr., a Democrat from Virginia — have promoted it as a way to curb abuse of the I.T.C. by patent trolls. It would prohibit patent holders from suing unless they manufactured a product that used the patented technology or had licensed the technology to someone else already.

AliveCor and Masimo are medical companies that have focused on selling products to health care providers and consumers more than licensing innovations to consumer technology companies like Apple.

Last year, Apple's lobbyists filed three reports disclosing that it had campaigned on behalf of the bill, according to Open Secrets, a campaign finance research nonprofit. It also added to its lobbying ranks by hiring Deanna Tanner Okun, a former I.T.C. chair who works for the law firm Polsinelli. (The hiring was previously reported by Politico.)

The lobbying campaign coincided with an effort to argue in Washington that an I.T.C. ban on Apple Watch imports would deprive people of a device that was crucial to their health, two people familiar with the lobbying said.

In addition to lobbying directly on legislation, Apple worked with a member of Congress to put language on Page 97 of a committee report for the 2024 Appropriations Bill, said Representative Ken Buck, a Republican from Colorado. The language would require the I.T.C. to review how it determined the value to the public of a product before suggesting a ban and to report to Congress on that process.

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Apple Steps Up Its Lobbying to Change Patent Rules - The New York Times



Representative Ken Buck said Apple had played a role in adding language to a bill that would affect the I.T.C. Kenny Holston/The New York Times

“To me, this went around the legitimate process,” said Mr. Buck, who is leaving Congress this month. He told Representative Thomas Massie, a Republican from Kentucky who is on the Rules Committee, that he had 10 votes and would block the bill unless the language was removed. Mr. Massie’s office confirmed that the language had been removed at Mr. Buck’s request but declined to comment further.

An Apple spokeswoman disagreed with Mr. Buck’s claims that its lobbying circumvented the legitimate legislative process. She said its public federal lobbying reports detailed how it worked on issues important for its products and customers.

The spokeswoman also pointed to the Senate’s passage of a committee report with a sentence expressing its support of the I.T.C.’s doing thorough analysis of the public health implications of a product ban before issuing one, which is what Apple wants in the future.

Tripp Mickle reports on Apple and Silicon Valley for The Times and is based in San Francisco. His focus on Apple includes product launches, manufacturing issues and political challenges. He also writes about trends across the tech industry, including layoffs, generative A.I. and robot taxis. More about Tripp Mickle

4/10/24, 3:01 PM

Apple Steps Up Its Lobbying to Change Patent Rules - The New York Times

A version of this article appears in print on , Section B, Page 1 of the New York edition with the headline: Apple Aims To Rewrite Patent Rules

CERTIFICATE OF SERVICE

I hereby certify that, on this 7th day of August, 2024, I filed the Non-Confidential Joint Appendix with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ Mark D. Selwyn

MARK D. SELWYN

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